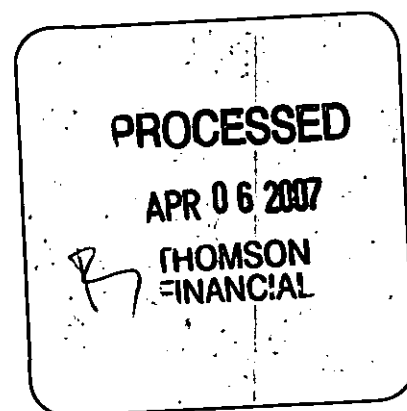


Annual Report 2006



The Adolor pipeline also includes a combination product development program, where we intend to combine alvimopan with an opioid in a single formulation. Our primary focus here is on a combination of hydrocodone/APAP with alvimopan.

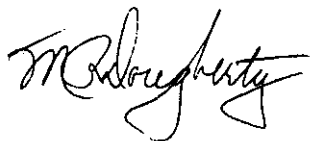
Hydrocodone is the most widely prescribed opioid for acute use, with more than 90 million prescriptions written per year in the United States. Progress in 2006 in this program was considerable. We prepared a combination product formulation, conducted a successful pharmacokinetic study, and initiated a co-administration clinical study in rotator cuff surgery patients. We look ahead to reporting initial findings from this study later this year.

We also saw progress in 2006 on our Delta Opioid Receptor Agonist Program. Currently marketed opioids interact primarily with the Mu opioid receptor, and, by contrast, the Delta receptor has proven to be an elusive target in analgesic product development. We have been focused on opioid receptor technology since our inception at Adolor and are pleased to have now advanced our lead Delta compound into human clinical safety testing. We hope to do the same for a second Delta compound later this year. Based on preclinical models, Delta compounds may find application in a variety of pain conditions, including Mu-tolerant pain, cancer pain and inflammatory pain, with a potentially different side effect profile as compared to Mu-opioid agonists. We expect to begin proof-of-concept efficacy studies later this year and are currently evaluating indications in which to do so.

Just as the Delta program was nurtured by our Discovery Team over a period of years, so too talented scientists at Adolor are now working on other potential drug targets including targets outside of the opioid receptor arena. Ours is a small research group, but we find our strength in our focus. We quickly and precisely assess ideas, targets, and technology advances, and bring forward only those which show the most promise. Our internal research efforts are supplemented by a vigorous assessment of external in-licensing or acquisition opportunities; indeed discovery and business development are company-wide initiatives at Adolor.

As we look back, 2006 brought some difficulties we certainly did not expect. We go forward with a conviction and resolve strengthened from this experience. I thank our stockholders for their support. I thank our employees for their dedication and for the passion with which they go about their daily endeavors. And, finally, I thank David Madden, our Chairman of the Board, for his significant contributions and exemplary commitment to Adolor throughout his tenure as interim president and chief executive officer.

I look forward to reporting on our progress throughout the year.



Michael R. Dougherty

President and Chief Executive Officer

March 16, 2007

Dear Stockholders:

One measure of the strength and resiliency of a company is how well it handles a period of adversity. Most certainly, Adolor encountered a number of unexpected setbacks in 2006. With these setbacks though, we are now presented with an opportunity; the opportunity to respond to our current challenges and become a stronger company as a result.

I believe in Adolor and am proud to serve as the company's president and chief executive officer. In this, my first letter to stockholders, I will review our business, our plans to address current challenges and the vision of success I share with the entire team here at Adolor.



As a company, we have many strengths: a talented research and development team; a lead product which addresses a substantial market need; a developing earlier stage pipeline; and a solid financial position. Importantly, our focus in pain management is very well placed. Pain management as a field is in need of creativity, innovation and, ultimately, new products. Adolor is well positioned to develop those products.

Our lead product candidate, Entereg® (alvimopan), has the potential to provide significant benefits to patients who suffer the gastrointestinal complications that opioid analgesics often present. In November 2006, the U.S. Food and Drug Administration (FDA) issued an approvable letter for our New Drug Application (NDA) for the management of postoperative ileus (POI) following bowel resection surgery. In this letter, the FDA asked us to provide 12-month safety data, including an analysis of serious cardiovascular events, from an ongoing safety study, Study 014, and also requested that we provide a risk management plan as part of any resubmission for approval.

We were obviously disappointed to receive a second approvable letter for the POI indication. Our perspective though is clear; we continue to believe in the safety and efficacy of Entereg and remain committed to its development. Our plan forward is to act prudently, yet promptly. A complete response to this approvable letter is targeted to be submitted in the second quarter of 2007. We expect that this submission will trigger a six-month review period at the FDA, which would yield a late 2007 action date with regard to the application. If the FDA favorably reviews our response, an approval of Entereg in this indication could occur late this year. We are working quite diligently even now to affect this timeline.

At the time of this writing, we are also working with our collaborator, GlaxoSmithKline (GSK), in planning potential next steps in the development of Entereg in opioid-induced bowel dysfunction. GSK expects to conduct an additional safety and efficacy study, Study 015. GSK has submitted a Special Protocol Assessment (SPA) for Study 015 to seek FDA review and agreement on its design and size and is targeting the second quarter of 2007 to begin this study. We look forward to updating you further as events progress.

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For Fiscal Year Ended December 31, 2006

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from _____ to _____
Commission File 000-30039

ADOLOR CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation or organization)

700 Pennsylvania Drive, Exton, Pennsylvania
(Address of principal executive offices)

31-1429198

(IRS Employer
Identification Number)

19341
(Zip Code)

(484) 595-1500

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)

(Name of each exchange on which registered)

Common Stock, \$0.0001 par value
Series A Junior Participating Preferred Stock
Purchase Rights

The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Act. Check one:

Large accelerated filer ☒

Accelerated filer ☐

Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

The approximate aggregate market value of Common Stock held by non-affiliates of the registrant was \$1,097,961,209 as of June 30, 2006, the last business day of the registrant's most recently completed second fiscal quarter. (For purposes of determining this amount only, the registrant has defined affiliates as including (a) the executive officers of the registrant as of June 30, 2006; and (b) all directors of the registrant as of June 30, 2006.

The number of shares of the registrant's Common Stock outstanding as of February 22, 2007 was 45,999,843.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement (the "Definitive Proxy Statement") to be filed with the Securities and Exchange Commission in connection with the Company's Annual Meeting of Stockholders for the fiscal year ended December 31, 2006 are incorporated by reference into Part III of this Report.

ADOLOR CORPORATION

FORM 10-K

December 31, 2006

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PART I

ITEM 1. BUSINESS

Forward-Looking Statements

Various statements made in this Annual Report on Form 10-K are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those which express plan, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. We have based these forward-looking statements on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown which could cause actual results and developments to differ materially from those expressed or implied in such statements. These forward-looking statements include statements about the following:

- the status and anticipated timing of regulatory review and approval, if any, for our product candidates;
- our product development efforts, including results from clinical trials;
- anticipated dates of clinical trial initiation, completion and announcement of trial results by us and our collaborators;
- anticipated trial results and regulatory submission dates for our product candidates by us and our collaborators;
- analysis and interpretation of data by regulatory authorities;
- anticipated operating losses and capital expenditures;
- our intentions regarding the establishment of collaborations;
- anticipated efforts of our collaborators;
- estimates of the market opportunity and the commercialization plans for our product candidates;
- our intention to rely on third parties for manufacturing;
- the scope and duration of intellectual property protection for our products;
- the scope of third party patent rights;
- our ability to raise additional capital; and
- our ability to acquire or in-license products or product candidates.

In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "could", "would", "expect", "plan", "anticipate", "believe", "estimate", "target", "goal", "continue", or the negative of such terms or other similar expressions. Factors that might cause or contribute to differences include, but are not limited to, those discussed in Item 1A. Risk Factors of this Annual Report and discussed in our other Securities and Exchange Commission ("SEC") filings.

We urge you to carefully review and consider the disclosures found in these filings, all of which are available in the SEC EDGAR database at www.sec.gov. Given the uncertainties affecting pharmaceutical companies in the development stage, you are cautioned not to place undue reliance on any such forward-looking statements, any of which may turn out to be wrong due to inaccurate assumptions, unknown risks, uncertainties or other factors. We undertake no obligation to (and expressly disclaim any such obligation to) publicly update or revise the statements made herein or the risk factors that may relate thereto whether as a result of new information, future events or otherwise.

The following discussions should be read in conjunction with our audited Consolidated Financial Statements and related notes thereto included elsewhere in this Annual Report and the Risk Factors in Item 1A of this Report.

Our Company

We are a development stage biopharmaceutical corporation that was formed in 1993. Since inception, we have specialized in the discovery and development of prescription pain management products and expect to commercialize products that are successfully developed. We have a number of product candidates in various stages of development, ranging from preclinical studies to pivotal clinical trials. Our most advanced product candidate, *Entereg*® (alvimopan), is intended to selectively block the unwanted effects of opioid analgesics on the gastrointestinal (GI) tract. For the global development and commercialization of *Entereg* as a monotherapy, we are collaborating with Glaxo Group Limited (Glaxo) in multiple indications. Separately, we are also developing products that combine alvimopan with an opioid analgesic. In addition to products based on alvimopan, we are developing a delta opioid agonist which is currently in phase I clinical safety testing. Additional product candidates are in preclinical development for the treatment of moderate-to-severe pain conditions.

Entereg® (alvimopan)

Opioid analgesics provide pain relief by stimulating opioid receptors located in the central nervous system. There are, however, opioid receptors throughout the body, including the GI tract. By binding to the receptors in the GI tract, opioid analgesics can slow gut motility and disrupt normal GI function that allows for the passage, absorption and excretion of ingested solid materials. This disruption can cause patients to experience significant discomfort and abdominal pain and may result in their reducing or eliminating their pain medication.

Entereg is a small molecule, *mu*-opioid receptor antagonist intended to block the adverse side effects of opioid analgesics on the GI tract without affecting analgesia. We are developing *Entereg* for both acute and chronic conditions. The acute indication currently under development is the management of postoperative ileus (POI), a GI condition characterized by the slow return of gut function that can result from GI or other surgeries. *Entereg* is also being developed to treat opioid-induced bowel dysfunction (OBD), which is a condition characterized by a number of GI symptoms, including constipation, that often results from chronic use of opioid analgesics to treat persistent pain conditions.

In April 2002, we entered into a collaboration agreement with Glaxo for the exclusive worldwide development and commercialization of *Entereg* for certain indications. We are responsible for development of acute indications, such as POI, and Glaxo is responsible for development of chronic indications, such as OBD. In the United States, we and Glaxo are co-developing *Entereg* and intend to share profits that result from the sale of the product. For commercial sales of *Entereg* for POI in the United States, we would receive 45% and Glaxo would receive 55% of the net sales less certain agreed upon costs, and subject to certain adjustments. After the first three years each party's share would become 50%. For commercial sales of *Entereg* for OBD in the United States, we would receive 35% and Glaxo would receive 65% of the net sales less certain agreed upon costs, and subject to certain adjustments. Under the collaboration agreement, we have the right to convert our right to receive a profit share for OBD in the United States to a royalty on net sales of 20%. Outside the United States, Glaxo is responsible for the development and commercialization of *Entereg*, and we would receive royalties on net sales. We may receive additional milestone payments under the collaboration agreement upon the successful achievement, if any, of certain clinical and regulatory objectives, including up to \$40 million related to the POI indication and up to \$25 million related to the OBD indication.

POI Development Program

Regulatory Overview

We have invested a significant portion of our time and financial resources since our inception in the development of *Entereg*, and our potential to achieve revenues from product sales in the foreseeable future is

dependent largely upon obtaining regulatory approval for and successfully commercializing *Entereg*, especially in the United States. We have completed four Phase III clinical studies of *Entereg* for the management of POI, and submitted a New Drug Application (NDA) for *Entereg* 12 mg capsules to the Food and Drug Administration (FDA) in June 2004. Additionally, Glaxo has completed a Phase III study evaluating *Entereg* in POI conducted in Europe, Australia and New Zealand (Study 001). Our NDA was amended in April 2005 to include data from Study 001.

In November 2006, we announced the receipt of our second approvable letter from the FDA for *Entereg* 12 mg capsules, under review for the management of POI by acceleration of GI function following bowel resection surgery. An approvable letter is a letter from the FDA to an NDA applicant indicating that the FDA may approve the NDA if specific additional information is submitted or specific conditions are agreed upon. The November 2006 approvable letter indicated that before the application for *Entereg* may be approved, it will be necessary to provide the twelve-month safety data, including analysis of serious cardiovascular events from study 767905/014 (Study 014), an ongoing safety study being conducted by Glaxo in OBD. The FDA's review of the NDA for POI included a six-month interim analysis of Study 014. The Study 014 interim analysis showed an increase, which was not statistically significant, in the reported incidence of serious cardiovascular adverse events in patients receiving alvimopan as compared to patients receiving placebo. The FDA also requested a risk management plan.

On December 14, 2006, we announced that we were disbanding our sales force of approximately 35 people and made other selected reductions to our workforce due to receipt of our second approvable letter from the FDA.

Glaxo recently completed last patient last visit for Study 014, with top-line results expected to be available by the second quarter of 2007. We expect to submit Study 014 data, along with a proposed risk management plan, in a complete response to the November 2006 approvable letter in the second quarter of 2007.

In July 2005, we received our first approvable letter from the FDA. The July 2005 approvable letter indicated that before the application for *Entereg* may be approved, it will be necessary to provide additional proof of efficacy to the FDA to support the use of *Entereg* following bowel resection surgery. The FDA indicated that this may be achieved by demonstrating statistically significant results in at least one additional clinical study, and that this could potentially be addressed with positive results from our Study 14CL314 (Study 314). Results from Study 314 were announced in February 2006. The FDA also indicated that we must provide justification that the median reduction in time to gastrointestinal recovery seen in bowel resection patients treated with *Entereg* is clinically meaningful. Following completion of Study 314, we submitted a complete response to the July 2005 NDA approvable letter. The FDA issued the November 2006 NDA approvable letter at the conclusion of its review.

Clinical Overview

Our *Entereg* POI Phase III clinical program in support of the NDA submitted in June 2004 included four studies. Three of these studies (POI 14CL302, POI 14CL308 and POI 14CL313) were double-blind, placebo-controlled multi-center studies, each designed to enroll patients scheduled to undergo certain types of major abdominal surgery and receiving opioids for pain relief. Under the protocols, patients were randomized into three arms to receive placebo, 6 mg or 12 mg doses of *Entereg*. The primary endpoint in these three efficacy studies was time to recovery of GI function (GI3), a composite measure of the time to recovery of both upper and lower GI function, as defined by time to tolerability of solid foods, and time to first flatus or first bowel movement, whichever occurred last. The fourth POI clinical study in our Phase III program, POI 14CL306, was a double-blind, placebo-controlled multi-center observational safety study under which patients were randomized to receive either *Entereg* 12 mg (413 patients) or placebo (106 patients). GI3 was included as one of the secondary endpoints in the study. Glaxo also completed a Phase III study (Study 3B 767905/001), Study 001, evaluating *Entereg* in POI.

We have also conducted an additional study in support of our pending NDA, Study 314. The protocol for Study 314 provides that the initial dose of *Entereg* should be administered 30 to 90 minutes prior to surgery, as compared to our previous Phase III studies where the first dose was required to be administered (at least) 120 minutes prior to surgery. The primary endpoint of Study 314 is time to recovery of GI function, GI2, a composite

measure of the time to recovery of both upper and lower GI function, as defined by time to tolerability of solid foods, and time to first bowel movement, whichever occurred last. Study 314 was also designed to evaluate certain secondary endpoints.

Study 302. In April 2003, we announced top-line results of our first POI Phase III clinical study, POI 14CL302. Study POI 14CL302 enrolled 451 patients and was designed to include large bowel resection patients and radical hysterectomy patients, as well as simple hysterectomy patients (22% of enrolled patients). A statistically significant difference was achieved in the primary endpoint of the study in patients in the *Entereg* 6 mg treatment group compared to patients in the placebo group (Cox proportional hazard model, hazard ratio = 1.45; $P < 0.01$). A positive trend was observed in the primary endpoint of the study for the *Entereg* 12 mg treatment group; however, the difference from placebo was not statistically significant (Cox proportional hazard model, hazard ratio = 1.28; $P = 0.059$). A difference in favor of the *Entereg* treatment groups versus placebo was observed for all secondary endpoints, including time to hospital discharge order written. The most frequently observed adverse events in both the placebo and treatment groups were nausea, vomiting and abdominal distension.

The hazard ratio measures the degree of difference between the study drug group and the placebo group. A hazard ratio of 1 would indicate no difference between the study drug group and the placebo group in the probability of achieving the endpoint. A hazard ratio of 1.5 means that subjects receiving drug are 50% more likely to achieve the endpoint, on average, during the course of the data collection period. Statistical analyses estimate the probability that an effect is produced by the drug. This probability is generally expressed as a "P value" which is an estimate of the probability that any difference measured between the drug group and the placebo group occurred by chance. For example, when a P value is reported as $P < 0.05$, the probability that the study demonstrated a drug effect by chance is less than 5%.

Study 313. In September 2003, we announced top-line results of our second POI Phase III clinical study, POI 14CL313. Study POI 14CL313 enrolled 510 patients and was designed to include large bowel resection patients, small bowel resection patients and radical hysterectomy patients, and exclude simple hysterectomy patients. A statistically significant difference was achieved in the primary endpoint of the study, time to recovery of GI function, in both the *Entereg* 6 mg and 12 mg treatment groups compared to the placebo group (Cox proportional hazard model; for 6 mg group, hazard ratio = 1.28; $P < 0.05$; for 12 mg group, hazard ratio = 1.54; $P < 0.01$). A difference in favor of *Entereg* was observed for all of the secondary endpoints in both the 6 mg and 12 mg treatment groups, including time to hospital discharge order written. The most frequently observed adverse events in both the placebo and treatment groups were nausea, vomiting and hypotension.

Study 306. In October 2003, we announced top-line results of our third POI Phase III clinical study, POI 14CL306, which enrolled 519 patients. This study was designed to assess safety as its primary endpoint, and to assess efficacy as a secondary endpoint and to enroll only patients scheduled to undergo simple hysterectomy procedures. Study POI 14CL306 was the first study where dosing continued on an out-patient basis after patients were discharged from the hospital. *Entereg* was generally well tolerated in this observational safety study with 93% of patients completing treatment in the *Entereg* 12 mg treatment group and 92% of patients completing treatment in the placebo group. The most frequently observed adverse events in both the placebo and treatment groups were nausea, vomiting and constipation. The results in GI3, one of the secondary endpoints in the study, were not statistically significant as compared to placebo.

Study 308. In January 2004, we announced top-line results of our fourth POI Phase III clinical study, POI 14CL308. Study POI 14CL308 enrolled 666 patients, and was designed to include large bowel resection patients, small bowel resection patients and radical hysterectomy patients, as well as simple hysterectomy patients (14% of enrolled patients). A positive trend was observed in the primary endpoint of the study when each of the *Entereg* 6 mg and 12 mg treatment groups was compared to the placebo group (Cox proportional hazard model; for 6 mg group, hazard ratio = 1.20, $P = 0.08$; for 12 mg group, hazard ratio = 1.24, $P = 0.038$). Due to the multiple

dose comparison to a single placebo group, a P-value of less than 0.025 would have been required in the 12 mg dose group to be considered statistically significant. A difference in favor of *Entereg* was observed for all of the secondary endpoints in both the 6 mg and 12 mg treatment groups, including time to hospital discharge order written. The most frequently observed adverse events in both the placebo and treatment groups were nausea, vomiting and pruritis.

Study 001. In December 2004, we reported top-line results from a Phase III clinical study of *Entereg* in POI, Study 001. Study 001 was conducted in Europe, Australia and New Zealand by Glaxo and enrolled 741 bowel resection patients, and 170 radical hysterectomy patients. The prespecified primary analysis group only included the bowel resection patients. The primary endpoint results (GI3) of the study were (Cox proportional hazard model) for the 6 mg group, hazard ratio = 1.22 (P=0.042); and for the 12 mg group, hazard ratio = 1.13 (P=0.20), each as compared to placebo. These results are not statistically significant; due to the multiple dose comparison to a single placebo group, a P-value of less than 0.025 would be required in the 6 mg dose group to be considered statistically significant. The most frequently observed adverse events were nausea, vomiting and pyrexia.

Study 314. In February 2006, we announced top-line results of our Phase III clinical study, POI 14CL314, which enrolled 654 patients scheduled to undergo large or small bowel resection. For the primary GI2 endpoint of Study 314, a statistically significant difference was achieved as compared to placebo (Cox proportional hazard model) hazard ratio = 1.53, P<0.001. A statistically significant difference in favor of *Entereg* was achieved for each of the secondary time to event endpoints. Under the protocol, patients were randomized to receive placebo or 12 mg of *Entereg* twice daily. While GI3 was the primary endpoint for pivotal studies in our NDA, GI2 has been measured in each study. The data for the effect on time to GI2 recovery for bowel resection patients (MITT population) for the 12 mg dose of *Entereg* as an additional analysis is as follows: in Study 302, the hazard ratio was 1.400 and the P-value 0.029; in Study 308, the hazard ratio was 1.365 and the P-value 0.017; in Study 313, the hazard ratio was 1.625 and the P-value <0.001; and in Study 001, the hazard ratio was 1.299 and the P-value 0.008. The most frequently observed adverse events were nausea, vomiting and abdominal distension.

OBD Clinical Development Program

Entereg is being developed by Glaxo for the treatment of OBD in patients taking opioid analgesics for persistent pain conditions. In September 2006, we and Glaxo announced the top-line results from two Phase III registration studies, Studies SB-767905/012 (Study 012) and SB-767905/013 (Study 013) of alvimopan for the treatment of OBD in patients with chronic non-cancer pain, and one Phase 2b study, Study 767905/008 (Study 008) in patients with chronic cancer pain taking opioids and experiencing symptoms associated with OBD. Additionally, Glaxo recently completed last patient last visit for a Phase III long-term safety study, Study 014, and top-line results from this study are expected to be available by the second quarter of 2007.

Glaxo and we are currently planning potential next steps in the development of *Entereg* for OBD.

Study 012. In September 2006, we and Glaxo announced top-line results from a Phase III clinical study of *Entereg* in OBD, Study 012; a randomized, double-blind, placebo-controlled, multi-center study under which patients were randomized to one of two *Entereg* arms (0.5 mg once daily or 0.5 mg twice daily) or to placebo for twelve weeks of treatment. Study 012 enrolled 518 patients with chronic non-cancer pain who had experienced symptoms of OBD, defined as having less than 3 SBMs (defined as bowel movements with no laxative in the previous 24 hours) a week plus one or more bowel movement symptoms (incomplete evacuation, straining, hard/small pellets) for 25% of bowel movements. This study achieved statistical significance for the primary endpoint, the proportion of patients who had a weekly average of three or more SBMs and an increase from baseline of one or more SBMs a week over the 12-week treatment period. In patients treated with alvimopan 0.5 mg twice daily, 72% met the primary endpoint compared with 48% of patients receiving placebo (p less than 0.001). In patients treated with alvimopan 0.5 mg once daily, 61% met the primary endpoint compared with 48% of patients receiving placebo (p=0.065).

Study 013. In September 2006, we and Glaxo also announced top-line results from a Phase III clinical study of *Entereg* in OBD, Study 013, a randomized, double-blind, placebo-controlled, multi-center study under which patients were randomized to one of two *Entereg* arms (0.5 mg once daily or 0.5 mg twice daily) or to placebo for twelve weeks of treatment. Study 013 enrolled 485 patients with chronic non-cancer pain and its enrollment criteria and endpoints were identical to Study 012. In both groups of patients treated with alvimopan, 0.5 mg twice and once daily, over the 12-week treatment period, 63% met the primary endpoint, compared with 56% of patients receiving placebo ($p=0.214$ and $p=0.259$ respectively). These results are not statistically significant.

Entereg was generally well tolerated in Studies 012 and 013. Adverse events affecting the gastrointestinal (GI) tract were the most common in both studies occurring in 24-33% of alvimopan-treated patients, compared with 22% on placebo. These included abdominal pain, diarrhea, nausea and vomiting.

Study 008. In September 2006, we and Glaxo also announced top-line results from a Phase 2b clinical study of *Entereg* in patients with chronic cancer pain taking opioids and experiencing symptoms associated with OBD, Study 008. Study 008 enrolled 233 patients. The primary endpoint in this study was the change in frequency of spontaneous complete bowel movements (SCBMs), defined as a bowel movement with no laxative use in the previous 24 hours that provides the subject with a feeling of complete evacuation. The average weekly change from baseline for the three week treatment period was 1.9, 1.8 and 2.1 SCBMs for patients treated with alvimopan 0.5 mg twice daily, 1.0 mg once and twice daily, respectively, compared to 1.6 SCBMs in those receiving placebo. These differences were not statistically significant. The safety and tolerability of *Entereg* in this cancer pain study were similar to that seen in the placebo group.

Study 014. Study 014 is a randomized, double-blind, placebo-controlled study designed to enroll approximately 750 adults who are taking opioid therapy for persistent non-cancer pain and have OBD. Under the protocol, patients are randomized to *Entereg* (0.5 mg twice daily) or placebo for twelve months of treatment. The primary objective of this Phase III long-term safety study is to compare *Entereg* with placebo for safety and tolerability in the treatment of OBD. The primary safety endpoint is based on the frequency of reported adverse events. A six month interim analysis of Study 014 was submitted to the FDA in September 2006 in connection with the FDA's review of our NDA for POI. This analysis showed an increase, which was not statistically significant, in the reported incidence of serious cardiovascular adverse events in patients receiving *Entereg* as compared to patients receiving placebo.

Glaxo has recently completed last patient last visit for Study 014, with top-line results expected to be available by the second quarter of 2007. We expect to submit Study 014 data, along with a proposed risk management plan, in the complete response to the November 2006 approval letter in the second quarter of 2007.

Study SB767905/011 (Study 011). In March 2005, we and Glaxo announced top-line results from a Phase IIb study of *Entereg* in OBD. In Study 011, in 522 non-cancer patients with OBD, all three oral *Entereg* dosage regimens achieved statistically significant effects on the primary and secondary endpoints compared with placebo. The primary endpoint was the change from baseline in weekly frequency of SBMs over the first half of the 6-week treatment period. All groups reported an SBM frequency of approximately 1 per week during the baseline period. The average weekly change from baseline over weeks 1-3 was 3.36 SBM for the *Entereg* 0.5 mg, twice daily treatment group, 3.29 SBM for the *Entereg* 1mg, once daily treatment group and 4.17 SBM for the *Entereg* 1 mg, twice daily treatment group compared to 1.65 SBM for the placebo group. All *Entereg* treatment groups were statistically significantly different from placebo at the $P<0.001$ level. In this Phase IIb study adverse events affecting the GI tract were the most common, occurring in 30%-43% of *Entereg* treated patients, compared to 36% on placebo. The most frequently reported adverse events were abdominal pain, nausea and diarrhea and GI adverse events were also the most common reason for study withdrawal.

Combination Product

We are developing an analgesic product candidate that combines alvimopan and an opioid analgesic. This combination is intended to produce the pain relief of an opioid while reducing constipating side effects. During the second quarter of 2006 we commenced a Phase II dose ranging study in which alvimopan is co-administered with hydrocodone/APAP. This study is designed to enroll up to 300 patients undergoing ambulatory shoulder surgery for rotator cuff repair.

We also filed an Investigational New Drug Application (IND) for a coformulated hydrocodone/APAP and alvimopan product and have completed a phase I pharmacokinetic study which showed comparable drug levels in the co-formulated product and co-administered products.

Sterile Patch Program (ADL 8-7223)

We have determined not to continue pursuing development of our sterile lidocaine patch program. As a result, on October 27, 2006, we provided notice to EpiCept Corporation that we were terminating our License Agreement dated July 23, 2003, under which we licensed exclusive rights to develop and commercialize in North America a sterile lidocaine patch. Also as a result, on October 27, 2006, we provided notice to Corium International, Inc. that we were terminating our Scale Up and Commercial Supply Agreement dated November 16, 2005.

Delta Agonist Program

Through a proprietary research platform based on cloned, human opioid receptors, we have identified a series of novel, orally active *delta* agonists that selectively stimulate the *delta* opioid receptor. The *delta* receptor is one of three opioid receptors that modulate pain; the other receptors being the *mu* and *kappa* receptors. Today, all marketed opioid drugs interact with the *mu* receptors in the brain and spinal cord.

On the basis of preclinical evaluation in animal models of human conditions, one might expect a *delta* agonist to show effect in inflammatory pain, among other pain conditions. In addition, *delta* agonists are thought to modulate other biological processes that may manifest themselves in disease states or conditions such as overactive bladder and depression.

We are conducting Phase I clinical testing of our lead *delta* compound, ADL5859. During the third quarter of 2006, we commenced a Phase I clinical trial of ADL5859 designed to investigate the safety, tolerability and pharmacokinetics of a single dose of ADL5859 in healthy volunteers. We completed this single dose study in the fourth quarter of 2006 and are now conducting a multi-dose Phase I clinical study.

Discovery / In-Licensing

Our pain research efforts initially focused on designing small molecules to target peripheral opioid receptors as a means of avoiding the centrally mediated side effects of currently available opioid analgesics. While work continues on the selective targeting of peripheral opioid receptors, new research is using advancements in molecular biology and medicinal chemistry to design molecules to avoid prototypical opioid receptor-induced side effects. In addition, our discovery research team is actively assessing other, non-opioid pain targets. The overall goal of these programs is to develop medications that produce pain relief equal to or superior to traditional narcotics, while reducing or eliminating typical narcotic side effects.

We believe there are opportunities to expand our product portfolio through the acquisition or in-licensing of products and/or product development candidates and intend to continue to explore and evaluate such opportunities.

Competitive Environment

We operate in a highly regulated and competitive environment. Our competitors include fully integrated pharmaceutical companies and biotechnology companies, universities and public and private research

institutions. Many of the organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals, and greater manufacturing and marketing capabilities than we do.

Commercialization

We intend to maintain a strategic marketing group to support our research and development efforts and commercial activities. We do not currently maintain a sales force to sell any products we may develop. We had previously built a 35-person sales force intended to sell *Entereg* in the hospital market, but disbanded this sales force in December 2006.

In our collaboration agreement with Glaxo, for the POI indication for *Entereg*, we are required to provide a limited number of full-time equivalent sales personnel to sell the product. Under that agreement, we may request that Glaxo perform such sales effort, at our expense. If Glaxo does not choose to do so, we may engage a contract sales organization to provide such services. The discontinuation of our sales force does not affect the profit sharing arrangement in our collaboration agreement with Glaxo.

We have a small manufacturing organization to manage our relationships with third parties for the manufacture and supply of products for preclinical, clinical and commercial purposes. We maintain commercial supply agreements with certain of these third party manufacturers. We presently do not maintain our own manufacturing facilities.

In June 2004, we entered into a distribution agreement with Glaxo under which, upon our receipt of regulatory approvals, Glaxo will perform certain distribution and contracting services for *Entereg* on our behalf for a fee. Outside the United States, we intend to rely on Glaxo for sales and marketing of *Entereg* and expect to supply Glaxo with bulk capsules for commercial sale for POI under a supply agreement we entered into with Glaxo in September 2004.

As we develop additional product candidates we may enter into strategic marketing or co-promotion agreements with, and grant additional licenses to, pharmaceutical companies to gain access to additional markets both domestically and internationally.

Our Strategy

Our goal is to build a profitable pharmaceutical company specializing in the discovery, development and commercialization of prescription pain management products. We plan to pursue this objective by implementing the following strategies:

Focusing our Discovery Efforts Principally in the Area of Opioid Receptor Technology. We have focused our discovery efforts principally on clinical conditions that can be treated by either stimulating or blocking opioid receptors. These conditions include POI and chronic OBD, as well as various pain conditions, including inflammatory pain, itch and visceral pain. We have biological and chemical expertise to support drug discovery, including expertise in opioid receptors in analgesic pathways, cloned human opioid, orphan and chimeric receptors and the chemical synthesis of compounds that do not readily cross the blood-brain barrier.

We also maintain research efforts directed at the discovery and development of compounds that exert analgesic effects by targeting certain non-opioid receptors.

Implementing a Strategy that will Combine Third Party Alliances with our Internal Product Development and Marketing Efforts. We have built certain capabilities in discovery, development and commercialization in

advancing our product candidates. In addition, we have established and will continue selectively to establish collaborations with pharmaceutical companies and leading academic institutions to enhance our internal capabilities.

Implementing an In-Licensing/Acquisition Strategy. We believe there are opportunities to expand our product portfolios by the acquisition or in-licensing of products and/or product development candidates to complement our internal development efforts. We intend to explore in-licensing or acquisition of products or product candidates or technology, as well as acquisition of companies.

Background On Opioid Analgesia/Peripheral Receptors

Pain Transmission Signals. When tissues such as the skin, muscles and joints become inflamed or are injured, receptors in those tissues are activated, and electrical signals are transmitted from the injured tissues through nerve fibers into the spinal cord. Within the spinal cord, the electrical signals are received by a second set of nerve fibers that continue the transmission of the signal up the spinal cord and into the brain. Within the brain, additional nerve fibers transmit the electrical signals to the "pain centers" of the brain where these signals are perceived as pain. Receptors are also present in internal, or visceral, organs such as the intestines, uterus, cervix and bladder. These receptors also send signals via similar pathways to the brain when these organs are inflamed or distended, which are likewise perceived as pain.

Opioid Receptors Block Pain Transmission Signals. Opioid receptors located on the surface of nerves that modulate pain signals alter transmission of these pain signals when activated by drugs specific for those receptors. There are three major types of opioid receptors, *mu*, *kappa* and *delta*. Virtually all marketed opioid analgesic drugs interact with *mu*-opioid receptors in the brain and spinal cord. When these central nervous system *mu*-opioid receptors are activated with opioid analgesics such as morphine, the perception of pain is reduced. However, activating these opioid receptors in the central nervous system with morphine-like opioid analgesics often results in serious side effects such as sedation, decreased respiratory function and addiction. Because of the potential to cause addiction, drugs that are able to activate *mu*-opioid receptors in the brain (morphine-like opioid analgesics) are regulated, or scheduled, under the Controlled Substances Act.

Peripheral Opioid Receptors in the GI Tract. Just as there are opioid receptors on peripheral nerves that regulate the transmission of signals into the spinal cord, there are also opioid receptors in the gastrointestinal tract that regulate functions such as motility and water secretion and absorption. Stimulation of these gastrointestinal *mu*-opioid receptors by morphine, or other opioid analgesics, causes constipation associated with opioid bowel dysfunction. Scientists have shown that blocking these receptors with opioid receptor antagonist drugs during administration of morphine or other opioid analgesics may prevent or reverse the effects of opioid bowel dysfunction. However, currently marketed opioid receptor antagonist drugs also cross the blood-brain barrier and enter the brain where they can block the primary pain relieving effects of opioid analgesics such as morphine. These findings have created the opportunity to develop a new class of opioid antagonists, like *Entereg*, which, when taken with opioid analgesics, are designed to block the peripherally-mediated side effects of the opioid analgesics but not the desired analgesic activity of opioid drugs because they are designed not to cross the blood-brain barrier.

Collaboration and Other Agreements With Glaxo

In April 2002, we entered into a collaboration agreement with Glaxo for the exclusive worldwide development and commercialization of *Entereg* for certain indications. Under the terms of the collaboration agreement, Glaxo paid us a non-refundable and non-creditable signing fee of \$50.0 million during the quarter ended June 30, 2002. Additionally, in the third quarter of 2004, we recognized \$10.0 million in revenue under this agreement relating to achieving the milestone of acceptance for review of our NDA by the FDA. We may receive additional milestone payments under the collaboration agreement upon the successful achievement, if any, of certain clinical and regulatory objectives, including up to \$40 million related to the POI indication and up

to \$25 million related to the chronic OBD indication. The milestone payments relate to substantive achievements in the development lifecycle and it is anticipated that these will be recognized as revenue if and when the milestones are achieved.

We and Glaxo have agreed to develop *Entereg* for a number of acute and chronic indications which would potentially involve the use of *Entereg* in in-patient and out-patient settings. In the United States, we and Glaxo are co-developing *Entereg* and intend to share profits that result from the sale of product. For commercial sales of *Entereg* for POI in the United States, Adolor would receive 45% and Glaxo would receive 55% of the net sales, less certain agreed upon costs, and subject to certain adjustments. After the first three years each party's share would become 50%. For commercial sales of *Entereg* for OBD in the United States, we would receive 35% and Glaxo would receive 65% of the net sales less certain agreed upon costs, and subject to certain adjustments. Under the collaboration agreement, we have the right to convert our right to receive a profit share for OBD in the United States to a royalty on net sales of 20%. We have overall responsibility for development activities for acute care indications such as POI, and Glaxo has overall responsibility for development activities for chronic care indications such as OBD. Outside the United States, Glaxo is responsible for the development and commercialization of *Entereg* for all indications, and we would receive royalties on net sales, if any.

The term of the collaboration agreement varies depending on the indication and the territory. The term of the collaboration agreement for the POI indication in the United States is ten years from the first commercial sale of *Entereg* in that indication, if any. Generally, the term for the OBD indication in the United States is fifteen years from the first commercial sale of *Entereg* in that indication, if any. In the rest of the world, the term is generally fifteen years from the first commercial sale of *Entereg*, if any, on a country-by-country and indication-by-indication basis.

Glaxo has certain rights to terminate the collaboration agreement. Glaxo also has the right to terminate its rights and obligations with respect to the acute-care indications, or its rights and obligations for the chronic-care indications. Glaxo has the right to terminate the collaboration agreement for breach of the agreement by us or for safety related reasons as defined in the collaboration agreement. Glaxo's rights to terminate the acute-care indications or the chronic-care indications are generally triggered by failure to achieve certain milestones within certain timeframes, adverse product developments or adverse regulatory events. For example, because the POI product has not been commercially sold as of December 31, 2005, Glaxo now possesses the right to terminate the collaboration agreement with respect to the POI product and the OBD chronic product.

In June 2004, we entered into a distribution agreement with Glaxo under which, upon our receipt of regulatory approvals, Glaxo will perform certain distribution and contracting services for *Entereg* on our behalf for a fee. Outside of the United States we intend to rely on Glaxo for sales and marketing of *Entereg*, and expect to supply Glaxo with bulk capsules for sale under a supply agreement we entered into with Glaxo in September 2004.

External expenses for research and development and marketing activities incurred by each company in the United States are reimbursed by the other party pursuant to contractually agreed percentages. Contract reimbursement amounts owed to us by Glaxo are recorded gross on our Consolidated Statements of Operations as cost reimbursement under collaborative agreement revenue. Amounts reimbursable to Glaxo by us are recorded as research and development or marketing expense, as appropriate, on our Consolidated Statements of Operations.

License Agreements

In November 1996, Roberts Laboratories Inc. ("Roberts") licensed from Eli Lilly certain intellectual property rights relating to *Entereg*. In June 1998, we entered into an option and license agreement with Roberts under which we licensed from Roberts the rights Roberts had licensed from Eli Lilly for *Entereg*. We have made license and milestone payments under this agreement totaling \$1.6 million. If *Entereg* receives regulatory approval, we are obligated to make a milestone payment of \$900,000 under this agreement, as well as royalties

on commercial sales of *Entereg*. Our license to *Entereg* expires on the later of either the life of the last to expire of the licensed Eli Lilly patents or fifteen years from November 5, 1996, following which we will have a fully paid up license.

In August 2002, we entered into a separate license agreement with Eli Lilly under which we obtained an exclusive license to six issued U.S. patents and related foreign equivalents and know-how relating to peripherally selective opioid antagonists. We paid Eli Lilly \$4.0 million upon signing the agreement and are subject to additional clinical and regulatory milestone payments and royalty payments to Eli Lilly on sales, if any, of new products utilizing the licensed technology. Under this license agreement, we also agreed to pay Eli Lilly \$4.0 million upon acceptance for review of our NDA by the FDA, which payment was made in the third quarter of 2004.

We are a party to various license agreements that give us rights to use technologies and biological materials in our research and development processes. We may not be able to maintain such rights on commercially reasonable terms, if at all. Failure by us or our licensors to maintain such rights could harm our business.

Intellectual Property

We seek United States and international patent protection for important and strategic components of our technology. We also rely on trade secret protection for certain of our confidential and proprietary information, and we use license agreements both to access external technologies and assets and to convey certain intellectual property rights to others. Our commercial success will be dependent in part on our ability to obtain commercially valuable patent claims and to protect our intellectual property rights and to operate without infringing upon the proprietary rights of others.

We have rights to patents related to *Entereg* which expire between 2011 and 2020, including a U.S. patent claiming composition of matter which expires in 2011. We expect that the composition of matter patent may be eligible for patent term extension for five years. The scope of intellectual property protection provided during the period of patent term extension has been challenged in a number of legal cases. If we are granted patent term extension for an *Entereg* patent, we cannot be assured that any such extension will provide meaningful proprietary protection during the period of extension. One of the *Entereg* related U.S. patents claims the use of *Entereg* in postoperative ileus and another claims the combination of alvimopan plus an opioid agonist; both of these patents expire in 2020. These expiration dates are based on the presumption that the applicable maintenance fees are paid and the patents, if challenged, are not held to be invalid.

We filed a patent application in 2004 claiming composition of matter protection for our Delta product candidate, ADL5859. The claims of this patent application have not yet been examined by the U.S. Patent and Trademark Office.

The patent positions of pharmaceutical, biopharmaceutical and biotechnology companies, including ours, are generally uncertain and involve complex legal and factual questions. Our business could be negatively impacted by any of the following:

- the pending patent applications to which we have rights may not result in issued patents;
- the claims of any patents which are issued may not provide meaningful protection, may not provide a basis for commercially viable products or provide us with any competitive advantages;
- we may not be successful in developing additional proprietary technologies that are patentable;
- our patents may be challenged by third parties; and
- others may have patents that relate to our technology or business that may prevent us from marketing our product candidates unless we are able to obtain a license to those patents.

In addition, patent law relating to the scope of claims in the technology field in which we operate is still evolving. The degree of future protection for some of our rights, therefore, is uncertain. Furthermore, others may

independently develop similar or alternative technologies, duplicate any of our technologies, and if patents are licensed or issued to us, design around the patented technologies licensed to or developed by us. In addition, we could incur substantial costs in litigation if we have to defend ourselves in patent suits brought by third parties or if we initiate such suits.

With respect to proprietary know-how that is not patentable and for processes for which patents are difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. While we require all employees, consultants and potential business partners to enter into confidentiality agreements, we may not be able to protect adequately our trade secrets or other proprietary information. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets.

Government Regulation

In the United States, pharmaceutical and diagnostic products intended for use in humans are subject to rigorous FDA regulation. The process of completing clinical trials and obtaining FDA approvals for a new drug is likely to take a number of years and require the expenditure of substantial resources. There can be no assurance that any of our products will receive FDA approval.

The drug approval process

The process of drug development is complex and lengthy and the activities undertaken before a new pharmaceutical product may be marketed in the United States include:

- discovery research;
- preclinical studies;
- submission to the FDA of an IND, which must become effective before human clinical trials commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;
- submission to the FDA of a NDA; and
- FDA approval of the NDA prior to any commercial sale of the product.

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as animal studies and other studies to assess the potential safety and efficacy of the product candidate. The results of preclinical studies are then submitted to the FDA as a part of an IND and are reviewed by the FDA prior to the commencement of human clinical trials. Unless the FDA objects to, or otherwise responds to, an IND submission, the IND becomes effective 30 days following its receipt by the FDA.

Human clinical trials are typically conducted in three sequential phases that may overlap:

- Phase I: The drug is initially introduced into healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In addition, it is sometimes possible to conduct a preliminary evaluation of efficacy in Phase I trials for analgesia.
- Phase II: This phase involves studies in a limited patient population to identify possible adverse effects and safety risks, to evaluate the efficacy of the product for specific targeted diseases and to determine optimal dosage and tolerance.
- Phase III: When Phase II evaluations demonstrate that a dosage range of the product is effective and has an acceptable safety profile, Phase III trials are undertaken to further evaluate dosage, clinical efficacy and to further test for safety in an expanded patient population at geographically dispersed clinical study sites.

After clinical trials have been completed, the sponsor must submit to the FDA the results of the preclinical and clinical testing, together with, among other things, detailed information on the manufacture and composition

of the product, in an NDA. The FDA reviews the NDA and, if and when it determines that the data submitted are adequate to show that the product is safe and effective for its intended use, the FDA approves the NDA.

Other regulatory requirements

The FDA mandates that drugs be manufactured in conformity with current Good Manufacturing Practices (cGMP) regulations and at facilities approved to manufacture such drugs. If approval of an NDA is granted, requirements for labeling, advertising, record keeping and adverse experience reporting will also apply. In addition, if our products are approved for marketing by the FDA, we will be required to comply with several other types of state and federal laws applicable to pharmaceutical marketing. These laws include healthcare antikickback statutes and false claims statutes. Additionally, we may also be subject to regulations under other federal, state and local laws, including the Occupational Safety and Health Act, the Environmental Protection Act, the Clean Air Act, national restrictions on technology transfer, import, export, and customs regulations. Failure to comply with these requirements could result, among other things, in suspension of regulatory approval, recalls, injunctions, product seizures, non-coverage of our products under government health care programs or civil or criminal sanctions.

Whether or not FDA approval has been obtained, approvals of comparable governmental regulatory authorities in foreign countries must be obtained prior to the commencement of clinical trials and subsequent sales and marketing efforts in those countries. The approval procedure varies in complexity from country to country, and the time required may be longer or shorter than that required for FDA approval.

The federal Controlled Substances Act imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products. A principal factor in determining the particular requirements, if any, applicable to a product is its actual or potential abuse profile. A pharmaceutical product may be "scheduled" as a Schedule I, II, III, IV or V substance, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest. Because of the potential for abuse, drugs that are able to activate *mu*-opioid receptors in the brain (morphine-like opioid analgesics) are regulated, or scheduled, under the Controlled Substances Act. Any of our products that contain one of our product candidates in combination with narcotic analgesics will be subject to such regulation.

Available Information

We make available free of charge on or through our internet website at www.adolor.com, our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Employees

As of December 31, 2006, we had 128 full-time employees and one part-time employee. Most of our senior management and professional employees have had prior experience in pharmaceutical or biotechnology companies. None of our employees is covered by collective bargaining agreements. We believe that our relations with our employees are good.

ITEM 1A. RISK FACTORS

As further described herein, our performance and financial results are subject to risks and uncertainties including, but not limited to, the following specific risks:

We are highly dependent on achieving success in the clinical testing, regulatory approval and commercialization of our lead product candidate, Entereg, which may never be approved for commercial use.

We have invested a significant portion of our time and financial resources since our inception in the development of *Entereg*, and our potential to achieve revenues from product sales in the foreseeable future is dependent upon obtaining regulatory approval for and successfully commercializing *Entereg*, especially in the United States. Prior to commercialization of *Entereg* in the United States for any indication, the FDA would have to approve *Entereg* for commercial sale. Drug development is a highly uncertain process.

Entereg is under development in two indications, POI and OBD. With respect to POI, we received our second approvable letter from FDA for *Entereg* in November 2006, however, there is no assurance that the FDA will approve *Entereg* for POI in the future. With respect to OBD, we along with Glaxo announced in September 2006 that Study 012 achieved statistical significance in its primary endpoint while Study 013 did not achieve statistical significance in its primary endpoint.

We submitted a six-month interim analysis of Study 014 to the FDA in connection with our POI NDA. The interim analysis showed an increase in serious cardiovascular adverse events in patients receiving *Entereg* as compared to patients receiving placebo. Glaxo recently completed last patient last visit for Study 014 and top-line results from this study are expected to be available by the second quarter of 2007. Safety results in Study 014 may not support approval of *Entereg* for OBD, POI or any other indication. Additionally, foreign country regulatory approval is required prior to commercialization of *Entereg* outside of the United States. There is no assurance that Glaxo will seek approval of *Entereg* in countries outside the United States, or that such approval would be obtained.

We have received a second approvable letter from the FDA for Entereg in POI and our NDA for Entereg may not be approved.

In November 2006, we received a second approvable letter from FDA for *Entereg* in POI. The approvable letter indicated that before the application for *Entereg* may be approved, it will be necessary to provide the twelve-month safety data, including analysis of serious cardiovascular events from Study 014, a safety study being conducted by Glaxo in OBD. The FDA also requested a risk management plan. The Study 014 interim analysis showed an increase in the reported incidence of serious cardiovascular adverse events in patients receiving *Entereg* as compared to patients receiving placebo. Glaxo recently completed last patient last visit for Study 014 and top-line data from this study is expected to be available by the second quarter of 2007. There is no assurance that FDA will conclude that safety results in Study 014 support approval of *Entereg* for use in POI, OBD or any other indication.

In July 2005, we announced the receipt of our first approvable letter from the FDA for *Entereg* 12 mg capsules. The July 2005 NDA approvable letter indicated that before the application for *Entereg* may be approved, it will be necessary to provide additional proof of efficacy to the FDA to support the use of *Entereg* following bowel resection surgery. The FDA indicated that this may be achieved by demonstrating statistically significant results in at least one additional clinical study, and that this could potentially be addressed with positive results from Study 314. The FDA also indicated that we must provide justification that the median reduction in time to gastrointestinal recovery seen in bowel resection patients treated with *Entereg* is clinically meaningful. Following completion of Study 314, we submitted a complete response to the July 2005 NDA approvable letter. The FDA issued the November 2006 NDA approvable letter at the conclusion of its review.

There is no assurance that the FDA will conclude that the results of the *Entereg* studies support the approval of *Entereg* in POI. There is no assurance that the FDA will not raise additional issues, or that our NDA for

Entereg will ever be approved. FDA approval of our NDA is contingent on many factors, including a favorable risk/benefit assessment by the FDA. With regard to any studies we or Glaxo may conduct the FDA or other regulatory agencies may evaluate the results of such studies by different methods or conclude that the clinical trial results are not statistically significant or clinically meaningful, or that there were human errors in the conduct of the clinical trials or otherwise. Even if we believe we have met the FDA guidelines for submission of data and information to the NDA, there is a risk that the FDA will require additional data and information that may require additional time to accumulate, or that we are unable to provide.

Certain results from Phase III clinical trials showed that the differences in the primary endpoint analyses between Entereg and placebos were not statistically significant.

Our *Entereg* POI Phase III program initially consisted of four studies, POI 14CL302, POI 14CL313, POI 14CL308 and POI 14CL306. Based on the results from these studies we submitted an NDA for *Entereg* 12 mg capsules in June 2004. In study POI 14CL302, the difference from placebo in the primary endpoint, GI3, for the *Entereg* 12 mg treatment group was not statistically significant. In study POI 14CL308, the difference from placebo for GI3 was not statistically significant in either the *Entereg* 6 mg or the 12 mg treatment groups. Even though the P-value for the 12 mg dose group of study POI 14CL308 was below 0.05, it is not considered formally statistically significant because of the multiple dose comparison. In studies involving multiple dose comparisons, statisticians control the overall study error rate (i.e. the likelihood that the drug response occurred by chance) by requiring that each of the multiple dose comparisons meet a P-value of $P < 0.05$ to show statistical significance. In the event that one of the dose comparisons in any of these POI Phase III studies does not reach a significance level of $P < 0.05$, the other dose comparison in that study needs to reach a significance level of $P < 0.025$ to be considered statistically significant. In study POI 14CL306, GI3 was analyzed as one of the secondary efficacy endpoints, and the difference from placebo for this endpoint was not statistically significant.

Glaxo conducted a Phase III clinical study (Study 001) of *Entereg* in POI in Europe, Australia and New Zealand. Our NDA was amended in April 2005 to include data from Study 001. In this study, the difference from placebo in the primary endpoint, GI3, was not statistically significant in either the 6 mg or 12 mg treatment groups.

We along with Glaxo recently announced top-line results from two registration Phase III studies of *Entereg* for the treatment of OBD in patients with chronic non-cancer pain. In one of those studies, Study 013, the result in the primary endpoint was not statistically significant. We along with Glaxo also announced top-line results from a Phase 2b investigation of alvimopan in patients with cancer pain treated with opioid analgesics. The results in the primary endpoints for this Phase 2b study were not statistically significant.

These results or future results that fail to achieve statistical significance may make it more difficult to achieve regulatory approval of *Entereg* in POI, OBD or any other indication.

Even if we are able to achieve regulatory approval of Entereg for use in POI, a risk management plan may adversely affect the commercial prospects for Entereg.

The November 2006 approvable letter for the NDA for *Entereg* in POI indicated that we would need to develop a risk management plan. A risk management plan may include restrictions that adversely affect the commercial prospects for *Entereg*.

Entereg may not be successfully developed for chronic use.

In September 2006, we along with Glaxo announced the results from two identically designed Phase III registration studies in OBD in patients with chronic non-cancer pain conducted by Glaxo (Studies 012 and 013). Study 012 achieved statistical significance in its primary endpoint while Study 013 did not achieve statistical significance in its primary endpoint. We also announced top-line results from a Phase 2b investigation of

alvimopan in patients with cancer pain treated with opioid analgesics. The results in the primary endpoints for this Phase 2b study were not statistically significant.

Additionally, a six-month interim analysis of Study 014, a long-term safety study, showed an increase in the reported incidence of serious cardiovascular adverse events in patients receiving *Entereg* as compared to patients receiving placebo. Glaxo has recently completed last patient last visit in Study 014, with top-line results expected to be available by the second quarter of 2007.

Glaxo and Adolor are currently planning potential next steps in the development of *Entereg* for OBD. Results from Study 014 may make it more difficult to further develop *Entereg* for OBD, and make it more difficult to obtain approval in OBD, or other indications.

Unfavorable results or adverse safety findings from any clinical study will adversely affect our ability to obtain regulatory approval for Entereg or market acceptance of Entereg if it is approved.

The six-month interim analysis of Study 014 showed an increase in serious cardiovascular adverse events in patients receiving *Entereg* as compared to patients receiving placebo. The FDA may conclude that the results from Study 014 do not support regulatory approval of *Entereg* for POI, OBD or any indication, and even if we receive FDA approval, these data may adversely affect market acceptance for *Entereg*.

We and Glaxo expect to continue to clinically evaluate *Entereg* in both acute and chronic conditions. We are conducting, or planning to conduct, additional studies of *Entereg* and of our combination product in the United States. Unfavorable results in any study may adversely affect our ability to obtain FDA or other regulatory approval of *Entereg*, and even if approved, may adversely affect market acceptance for *Entereg*.

Additional clinical trials of *Entereg*, conducted by us or our collaborator, Glaxo, could produce undesirable or unintended side effects that have not been evident in our clinical trials conducted to date. In addition, in patients who take multiple medications, drug interactions with *Entereg* could occur that can be difficult to predict. Assessing clinical trial results of *Entereg* in combination with narcotic analgesics may also add to the complexity of interpreting the study results.

If we are unable to commercialize Entereg, our ability to generate revenues will be impaired and our business will be harmed.

We have not yet commercialized any products or technologies, and we may never do so. If *Entereg* is not approved by the FDA, our ability to achieve revenues from product sales will be impaired and our stock price will be materially and adversely affected. FDA approval is contingent on many factors, including clinical trial results and the evaluation of those results. Even if *Entereg* is approved by the FDA for marketing, we will not be successful unless *Entereg* gains market acceptance. The degree of market acceptance of *Entereg* will depend on a number of factors, including:

- the breadth of the indication for which *Entereg* may receive approval;
- the risk management plan;
- the interpretation by the medical community of the safety and clinical efficacy of *Entereg*;
- the potential advantages of *Entereg* over competitive products; and
- the pricing and reimbursement policies of government and third-party payors, such as insurance companies, health maintenance organizations and other plan administrators.

Physicians, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend *Entereg*.

Patient enrollment may be slow and patients may discontinue their participation in clinical studies, which may negatively impact the results of these studies, and extend the timeline for completion of our and our collaborator's development programs for our product candidates.

The time required to complete clinical trials is dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including:

- the size of the patient population;
- the nature of the clinical protocol requirements;
- the diversion of patients to other trials or marketed therapies;
- the ability to recruit and manage clinical centers and associated trials;
- the proximity of patients to clinical sites; and
- the patient eligibility criteria for the study.

We are subject to the risk that patients enrolled in our and our collaborator's clinical studies for our product candidates may discontinue their participation at any time during the study as a result of a number of factors, including, withdrawing their consent or experiencing adverse clinical events which may or may not be related to our product candidates under evaluation. We are subject to the risk that if a large number of patients in any one of our studies discontinue their participation in the study, the results from that study may not be positive or may not support an NDA for regulatory approval of our product candidates.

We may suffer significant setbacks in advanced clinical trials, even after promising results in earlier trials.

Product candidates that appear to be promising at earlier stages of development may not reach the market or be marketed successfully for a number of reasons, including, but not limited to, the following:

- researchers may find during later preclinical testing or clinical trials that the product candidate is ineffective or has harmful side effects;
- the number and types of patients available for extensive clinical trials may vary;
- new information about the mechanisms by which a drug candidate works may adversely affect its development;
- one or more competing products may be approved for the same or a similar disease condition, raising the hurdles to approval of the product candidate;
- the product candidate may fail to receive necessary regulatory approval or clearance; or
- competitors may market equivalent or superior products.

Our stock price may be volatile, and your investment in our stock could decline in value

The market price for our common stock has been highly volatile and may continue to be highly volatile in the future. For example, since January 1, 2006, the closing price of our common stock reached a low of \$6.95 per share on January 10, 2007, and a high of \$27.45 per share on March 2, 2006.

The market price for our common stock is highly dependent on the success of our product development efforts, and in particular, clinical trial results and regulatory review results.

The following additional factors may have a significant impact on the market price of our common stock:

- developments concerning our collaborations, including our collaboration with Glaxo;
- announcements of technological innovations or new commercial products by our competitors or us;

- developments concerning proprietary rights, including patents;
- publicity regarding actual or potential medical results relating to products under development by our competitors or us;
- regulatory developments in the United States and foreign countries;
- litigation;
- economic and other external factors or other disasters or crises;
- period-to-period fluctuations in our financial results; and
- the general performance of the equity markets and, in particular, the biopharmaceutical sector of the equity markets.

Following periods of volatility and decline in the market price of a particular company's securities, securities class action litigation has often been brought against that company.

We have been named in a purported class action lawsuit and related derivative lawsuits.

On April 21, 2004, a lawsuit was filed in the United States District Court for the Eastern District of Pennsylvania against us, one of our directors and certain of our officers seeking unspecified damages on behalf of a putative class of persons who purchased our common stock between September 23, 2003 and January 14, 2004. The complaint alleges violations of Section 10(b) and section 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), in connection with the announcement of the results of certain studies in the our Phase III clinical trials for *Entereg*, which allegedly had the effect of artificially inflating the price of the our common stock. This suit has been consolidated with three subsequent actions asserting similar claims under the caption: *In re Adolor Corporation Securities Litigation*, No. 2:04-cv-01728. On December 29, 2004, the district court issued an order appointing the Greater Pennsylvania Carpenters' Pension Fund as Lead Plaintiff. The appointed Lead Plaintiff filed a consolidated amended complaint on February 28, 2005. The Complaint purported to extend the class period, so as to bring claims on behalf of a putative class of Adolor shareholders who purchased stock between September 23, 2003 and December 22, 2004. The Complaint also adds as defendants our Board of Directors asserting claims against them and the other defendants for violation of Section 11 and Section 15 of the Securities Act of 1933 in connection with our public offering of stock in November 2003. We and our management and director defendants moved to dismiss the Complaint on April 29, 2005. The plaintiffs responded to the motion to dismiss on June 28, 2005, and the defendants' reply was filed on August 12, 2005. We believe that the allegations are without merit and intend to vigorously defend the litigation.

On August 2, 2004, two shareholder derivative lawsuits were filed in the United States District Court for the Eastern District of Pennsylvania, purportedly on behalf of us, against our directors and certain of our officers seeking unspecified damages for various alleged breaches of fiduciary duty and waste. The allegations are similar to those set forth in the class action complaints, involving the announcement of the results of certain studies in our Phase III clinical trials for *Entereg*. On November 12, 2004, the Derivative Plaintiff filed an amended Complaint. On December 13, 2004, we filed a motion challenging the standing of the Derivative Plaintiff to file the derivative litigation on its behalf. On December 13, 2004, our directors and officers moved to dismiss the Complaint for failure to state a claim. Plaintiffs responded to the Company's and our directors' and officers' motions on January 27, 2005. We and our directors and officers filed reply briefs on February 18, 2005.

We may become involved in additional litigation of this type in the future. Litigation of this type is often extremely expensive, highly uncertain and diverts management's attention and resources.

If we continue to incur operating losses for a period longer than anticipated, we may be unable to continue our operations.

We believe our existing cash, cash equivalents and short-term investments as of December 31, 2006 of approximately \$185.6 million will be sufficient to fund operations into 2009. We have generated operating losses

since we began operations in November 1994. We expect to continue to generate such losses and will need additional funds that may not be available in the future. We have no products that have generated any revenue and, as of December 31, 2006, we have incurred a cumulative net loss of approximately \$376.5 million. During the calendar years ended December 31, 2006, December 31, 2005 and 2004, we incurred operating losses of approximately \$79.3 million, \$60.2 million and \$46.1 million, respectively, and net losses of approximately \$69.7 million, \$56.8 million and \$43.6 million, respectively. We expect to incur substantial losses for at least the next several years and expect that these losses will increase as we expand our research and development and sales and marketing activities. If we fail to obtain the capital necessary to fund our operations, we will be forced to curtail our operations and we will be unable to develop products successfully. We do not know whether additional financing will be available when needed, or that, if available, we will obtain financing on terms favorable to our stockholders or to us. If adequate funds are not available on acceptable terms, our ability to fund our operations, products or technologies or otherwise respond to competitive pressures could be significantly delayed or limited, and we may have to reduce or cease our operations. If additional funds become available there can be no assurance that we can predict the time and costs required to complete development programs or that we will not substantially exceed our budgets.

We are dependent on our collaborators to perform their obligations under our collaboration agreements.

In April 2002, we and Glaxo entered into a collaboration agreement for the exclusive worldwide development and commercialization of *Entereg* for certain indications. We and Glaxo agreed to develop *Entereg* for a number of indications, both acute and chronic, which would potentially involve the use of *Entereg* in in-patient and out-patient settings. In the United States, we have the right to co-develop and to co-promote *Entereg* with Glaxo, and share development expenses and commercial returns, if any, pursuant to contractually agreed percentages. We have overall responsibility for the development of acute care indications such as POI, and Glaxo has overall responsibility for the development of chronic care indications such as OBD. We and Glaxo are required to use commercially reasonable efforts to develop the indications for which we and they are respectively responsible. We and Glaxo have established numerous joint committees to collaborate in the development of *Entereg*. These committees meet at regularly scheduled intervals. We depend on Glaxo to provide us with substantial assistance and expertise in the development of *Entereg*. Any failure of Glaxo to perform its obligations under our agreement could negatively impact our product candidate, *Entereg*, and could lead to our loss of potential revenues from product sales and milestones that may otherwise become due under our collaboration agreement and would delay our achievement, if any, of profitability. Glaxo has extensive experience in the successful commercialization of product candidates which would be difficult for us to replace if the collaboration agreement was not in place. In the near term, our success will largely depend upon the success of our collaboration with Glaxo to further develop *Entereg* and our success in obtaining regulatory approval to commercialize *Entereg*.

The term of the collaboration agreement varies depending on the indication and the territory. The term of the collaboration agreement for the POI indication in the United States is ten years from the first commercial sale of *Entereg* in that indication, if any. Generally, the term for the OBD indication in the United States is fifteen years from the first commercial sale of *Entereg* in that indication, if any. In the rest of the world, the term is generally fifteen years from the first commercial sale of *Entereg*, if any, on a country-by-country and indication-by-indication basis.

Glaxo has certain rights to terminate the collaboration agreement. Glaxo also has the right to terminate its rights and obligations with respect to the acute-care indications, or its rights and obligations for the chronic-care indications. Glaxo has the right to terminate the collaboration agreement for breach of the agreement by us or for safety related reasons as defined in the collaboration agreement. Glaxo's rights to terminate the acute-care indications or the chronic-care indications are generally triggered by failure to achieve certain milestones within certain timeframes, adverse product developments or adverse regulatory events. For example, because the POI product has not been commercially sold as of December 31, 2005, Glaxo now possesses the right to terminate the collaboration agreement with respect to the POI Product and the other products defined as the Adolor Products

and the OBD chronic product under the collaboration agreement. If Glaxo terminates the collaboration agreement, we may not be able to find a new collaborator to replace Glaxo, and our business will be adversely affected.

Our corporate collaborators, including Glaxo, may determine not to proceed with one or more of our drug discovery and development programs. If one or more of our corporate collaborators reduces or terminates funding, we will have to devote additional internal resources to product development or scale back or terminate some development programs or seek alternative corporate collaborators.

We have limited commercial manufacturing capability and expertise. If we are unable to contract with third parties to manufacture our products in sufficient quantities, at an acceptable cost and in compliance with regulatory requirements, we may be unable to obtain regulatory approvals, or to meet demand for our products.

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture a sufficient supply of our product candidates. We have depended and expect to continue to depend on third parties for the manufacture of our product candidates for preclinical, clinical and commercial purposes. We may not be able to contract for the manufacture of sufficient quantities of the products we develop, or even to meet our needs for pre-clinical or clinical development. Our products may be in competition with other products for access to facilities of third parties and suitable alternatives may be unavailable. Consequently, our products may be subject to delays in manufacture if outside contractors give other products greater priority than our products. It is difficult and expensive to change contract manufacturers for pharmaceutical products, particularly when the products are under regulatory review in an NDA process. Our dependence upon others for the manufacture of our products may adversely affect our future profit margin and our ability to commercialize products, if any are approved, on a timely and competitive basis.

To receive regulatory approval for *Entereg*, our contract manufacturers will be required to obtain approval for their manufacturing facilities to manufacture *Entereg*, and there is a risk that such approval may not be obtained. We are required to submit, in an NDA, information and data regarding chemistry, manufacturing and controls which satisfies the FDA that our contract manufacturers are able to make *Entereg* in accordance with cGMP. Under cGMPs, we and our manufacturers will be required to manufacture our products and maintain records in a prescribed manner with respect to manufacturing, testing and quality control activities. We are dependent on our third party manufacturers to comply with these regulations in the manufacture of our products and these parties may have difficulties complying with cGMPs. The failure of any third party manufacturer to comply with applicable government regulations could substantially harm and delay or prevent regulatory approval and marketing of *Entereg*.

We maintain a relationship with Torcan Chemical Ltd. for the supply of the active pharmaceutical ingredient ("API") in *Entereg*. We also maintain a relationship with Girindus AG as an additional supplier of API for *Entereg*. We maintain a relationship with Pharmaceuticals International Inc. for the supply of *Entereg* finished capsules, and a relationship with Sharp Corporation for the packaging of *Entereg* finished capsules. We also rely upon these parties for the performance of scale-up and other development activities, and for the maintenance and testing of product pursuant to applicable stability programs.

Clinical trials in our Phase III *Entereg* program use drug product incorporating active pharmaceutical ingredient manufactured by two different contract manufacturing facilities, one of which is no longer in business. Our efforts to obtain regulatory approval for *Entereg* may be impaired as a result of using material from two different contract manufacturing facilities.

We also expect to depend on third parties to manufacture product candidates we may acquire or in-license, and will need to develop our own internal capabilities and external relationships in that regard.

If we are unable to fully develop sales, marketing and distribution capabilities or enter into agreements with third parties to perform these functions, we will not be able to commercialize products.

We currently have no internal distribution capability, limited marketing capabilities, and no internal sales capabilities. In order to commercialize products, if any are approved, we must internally develop sales, marketing and distribution capabilities or make arrangements with third parties to perform these services. If we obtain regulatory approval, we intend to sell some products directly in certain markets and rely on relationships with established pharmaceutical companies to sell products in certain markets. To sell any of our products directly, we must fully develop a marketing and field force with technical expertise, as well as supporting distribution capabilities. We may not be able to establish in-house sales and distribution capabilities or relationships with third parties. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues may be lower than if we directly marketed and sold our products, and any revenues we receive will depend upon the efforts of third parties, which efforts may not be successful.

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval and depend on third parties to conduct our clinical trials.

We have limited experience in managing clinical trials, and delays or terminations of clinical trials we are conducting or may undertake in the future could impair our development of product candidates. Delay or termination of any clinical trials could result from a number of factors, including adverse events, enrollment requirements, rate of enrollment, competition with other clinical trials for eligible patients and other factors. We are subject to the risk that subjects enrolled in our clinical studies may discontinue their participation at any time during the study as a result of a number of factors, including, withdrawing their consent or experiencing adverse clinical events which may or may not be judged related to our product candidates under evaluation.

We contract with third parties to conduct our clinical trials, and are subject to the risk that these third parties fail to perform their obligations properly and in compliance with applicable FDA and other governmental regulations. The failure of any third party to comply with any governmental regulations would substantially harm our development efforts and delay or prevent regulatory approval of our product candidates.

Our ability to enter into new collaborations and to achieve success under existing collaborations is uncertain.

We have entered into, and may in the future enter into, collaborative arrangements, including our arrangement with Glaxo, for the marketing, sale and distribution of our product candidates, which require, or may require, us to share profits or revenues. We may be unable to enter into additional collaborative licensing or other arrangements that we need to develop and commercialize our product candidates. Moreover, we may not realize the contemplated benefits from such collaborative licensing or other arrangements. These arrangements may place responsibility on our collaborative partners for preclinical testing, human clinical trials, the preparation and submission of applications for regulatory approval, or for marketing, sales and distribution support for product commercialization. These arrangements may also require us to transfer certain material rights or issue our equity securities to corporate partners, licensees and others. Any license or sublicense of our commercial rights may reduce our product revenue. Moreover, we may not derive any revenues or profits from these arrangements.

We cannot be certain that any of these parties, including Glaxo, will fulfill their obligations in a manner consistent with our best interests. Collaborators may also pursue alternative technologies or drug candidates, either on their own or in collaboration with others, that are in direct competition with us.

Our quarterly operating results may fluctuate significantly depending on the initiation of new corporate collaboration agreements, the activities under current corporate collaboration agreements or the termination of existing corporate collaboration agreements.

Because our product candidates are in development, there is a high risk that further development and testing will demonstrate that our product candidates are not suitable for commercialization.

We have no products that have received regulatory approval for commercial sale. All of our product candidates, including *Entereg*, are in development, and we face the substantial risks of failure inherent in developing drugs based on new technologies. Our product candidates must satisfy rigorous standards of safety and efficacy before the FDA and foreign regulatory authorities will approve them for commercial use. To satisfy these standards, we will need to conduct significant additional research, animal testing, or preclinical testing, and human testing, or clinical trials.

Preclinical testing and clinical development are long, expensive and uncertain processes. Failure can occur at any stage of testing. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. Based on results at any stage of clinical trials, we may decide to discontinue development of our product candidates. Even if we obtain approval and begin marketing a product, on-going clinical trials, including for other indications, may result in additional information that could affect our ability or decision to continue marketing the drug.

We intend to explore opportunities to expand our product portfolio by acquiring or in-licensing products and/or product development candidates. Although we conduct extensive evaluations of product candidate opportunities as part of our due diligence efforts, there can be no assurance that our product development efforts related thereto will be successful or that we will not become aware of issues or complications that will cause us to alter, delay or terminate our product development efforts.

The concept of developing peripherally acting opioid antagonist drugs is relatively new and may not lead to commercially successful drugs.

Peripherally acting compounds given to patients as potential drugs are designed to exert their effects outside the brain and spinal cord, in contrast to centrally acting compounds which are designed to exert their effects on the brain or spinal cord. We are developing *Entereg* as a peripherally acting opioid antagonist. An opioid antagonist is designed to block the effects of the opioid at the receptor level; in the case of *Entereg*, it is designed to block the unwanted effects of opioid analgesics on the gastrointestinal tract. Since there are no products on the market comparable to our product candidates, we do not have any historical or comparative sales data to rely upon to indicate that peripherally acting opioid antagonist drugs will achieve commercial success in the marketplace. Market acceptance of our product candidates will depend on a number of factors, including:

- perceptions by members of the health care community, including physicians, of the safety and efficacy of our product candidates;
- cost-effectiveness of our product candidates relative to competing products;
- availability of government or third-party payor reimbursement for our product candidates;
- effectiveness of marketing and distribution efforts by us and our collaborators; and
- risk management plan.

Other products that are currently sold for pain management are already recognized as safe and effective and have a history of successful sales in the United States and elsewhere. Our new products in this area, if any, will be competing with drugs that have been approved by the FDA and have demonstrated commercial success in the United States and elsewhere. Drugs that have been on the market have safety and efficacy profiles that are generally better characterized than new drugs.

Reduction in the use of opioid analgesics would reduce the potential market for Entereg.

If the use of drugs or techniques which reduce the requirement for *mu*-opioids increases, the demand for *Entereg* would be decreased. Various techniques to reduce the use of opioids are used in an attempt to reduce the

impact of opioid side effects. The use of local anesthetics in epidural catheters during and after surgery with the continuation of the epidural into the post-operative period can reduce or eliminate the use of opioids. Non-steroidal inflammatory agents may also reduce total opioid requirements. Continuous infusion of local anesthetic into a wound or near major nerves can reduce the use of opioids in limited types of procedures and pain states. Novel analgesics which act at non-*mu*-opioid receptors are under development. Many companies have developed and are developing analgesic products that compete with opioids or which, if approved, would compete with opioids. If these analgesics reduce the use of opioids, it would have a negative impact on the potential market for *Entereg*.

If competitors develop and market products that are more effective, have fewer side effects, are less expensive than our product candidates or offer other advantages, our commercial opportunities will be limited.

Other companies have product candidates in development to treat the conditions we are seeking to ultimately treat and they may develop effective and commercially successful products. Our competitors may succeed in developing products either that are more effective than those that we may develop, or that they market before we market any products we may develop.

We believe that Progenics Pharmaceuticals, Inc. is developing methylnaltrexone for the treatment of indications like those being targeted by us in both the acute and chronic settings. There are products already on the market for use in treating irritable bowel syndrome which may be evaluated for utility in opioid induced bowel dysfunction. There may be additional competitive products about which we are not aware. If our competitors are able to reach the commercial market before we are, this could have a material adverse effect on our ability to reach the commercial market and sell our products.

Our competitors include fully integrated pharmaceutical companies and biotechnology companies, universities and public and private research institutions. Many of the organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals, and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to:

- attract qualified personnel;
- attract partners for acquisitions, joint ventures or other collaborations; and
- license proprietary technology.

Our Delta agonist program may not lead to successful drug candidates.

The *delta* receptor is one of three opioid receptors (*mu*, *delta* and *kappa*) that modulate pain. To date there have been no selective *delta* agonist compounds successfully developed and approved by the FDA. We submitted an IND to the FDA in December 2005 to begin clinical testing of our first novel oral *delta* agonist product candidate, ADL5859. In January 2006 we announced the FDA requested additional preclinical safety studies and additional information regarding our proposed Phase I protocol. Following our response to the FDA's request for additional studies and information, the FDA lifted the clinical hold on our *delta* IND for ADL5859. During the third quarter of 2006, we commenced a Phase I clinical trial of ADL5859 designed to investigate the safety, tolerability and pharmacokinetics of a single dose of ADL5859 in healthy volunteers. This Phase I study has been completed and we are conducting a Phase I multi-dose safety study of ADL5859.

Drug development is a highly uncertain process and we may not be successful in our *delta* agonist development program. Development of *delta* agonists may not lead to commercially successful drugs.

Our business could suffer if we cannot attract, retain and motivate skilled personnel and cultivate key academic collaborations.

We are a small company, and our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We may not be successful in attracting qualified individuals. Our success also depends on our ability to develop and maintain important relationships with leading academic institutions and scientists. Competition for personnel and academic collaborations is intense. In particular, our product development programs depend on our ability to attract and retain highly skilled chemists, biologists and clinical development personnel. If we lose the services of any of these personnel it could impede significantly the achievement of our research and development objectives. In addition, we will need to hire additional personnel and develop additional academic collaborations as we continue to expand our research and development activities. We do not know if we will be able to attract, retain or motivate personnel or maintain relationships. We do not maintain key man life insurance on any of our employees.

Companies and universities that have licensed technology and product candidates to us are sophisticated entities that could develop similar products to compete with products we hope to develop.

Licensing product candidates from other companies, universities, or individuals does not prevent such parties from developing competitive products for their own commercial purposes, nor from pursuing patent protection in areas that are competitive with us. The individuals who created these technologies are sophisticated scientists and business people who may continue to do research and development and seek patent protection in the same areas that led to the discovery of the product candidates that they licensed to us. The development and commercialization by us of successful products is also likely to attract additional research by our licensors and by other investigators who have experience in developing products for the pain management market. By virtue of their previous research activities, these companies, universities, or individuals may be able to develop and market competitive products in less time than might be required to develop a product with which they have no prior experience.

If we breach our licensing agreements, we will lose significant benefits and may be exposed to liability for damages.

We may breach our license agreements and may thereby lose rights that are important. We are subject to various obligations with respect to license agreements, including development responsibilities, royalty and other payments and regulatory obligations. If we fail to comply with these requirements or otherwise breach a license agreement or contract, the licensor or other contracting party may have the right to terminate the license or contract in whole or in part or change the exclusive nature of the arrangement. In such event we would not only lose all or part of the benefit of the arrangement but also may be exposed to potential liabilities for breach in the form of damages or other penalties.

Because we are not certain we will obtain necessary regulatory approvals to market our products in the United States and foreign jurisdictions, we cannot predict whether or when we will be permitted to commercialize any of our products.

The pharmaceutical industry is subject to stringent regulation by a wide range of authorities. We cannot predict whether we will obtain regulatory clearance for any product candidate we develop. We cannot market a pharmaceutical product in the United States until it has completed rigorous preclinical testing and clinical trials and the FDA's extensive regulatory premarket approval process. Satisfaction of regulatory requirements typically takes many years, is dependent upon the type, complexity and novelty of the product and requires the expenditure of substantial resources for research and development, testing, manufacturing, quality control, labeling and promotion of drugs for human use. Since neither the FDA nor international regulatory authorities have approved peripherally restricted narcotic antagonist drugs or *delta* agonist drugs for marketing, there is additional uncertainty as to whether our research and clinical approaches to developing new products for the pain

management market will lead to drugs that the FDA will consider safe and effective for indicated uses. Before receiving FDA approval to market a product, we must demonstrate that the product candidate is safe and effective in the patient population that is intended to be treated. Outside the United States, our ability to market a product is also contingent upon receiving a marketing authorization from the appropriate regulatory authorities, and is subject to similar risks and uncertainties.

We do not know whether our current or future preclinical and clinical studies will demonstrate sufficient safety and efficacy necessary to obtain the requisite regulatory approvals, or will result in marketable products. Any failure to adequately demonstrate the safety and efficacy of our product candidates will prevent receipt of FDA and foreign regulatory approvals and, ultimately, commercialization of our product candidates. Regulatory authorities may refuse or delay approval as a result of many other factors, including changes in regulatory policy during the period of product development and regulatory interpretations of clinical benefit and clinical risk. Regulatory clearance that we may receive for a product candidate will be limited to those diseases and conditions for which we have demonstrated in clinical trials that the product candidate is safe and efficacious. Even if we receive regulatory approval for our product candidates we must comply with applicable FDA post marketing regulations governing manufacturing, promotion, labeling, and reporting of adverse events and other information, as well as other regulatory requirements. Failure to comply with applicable regulatory requirements could subject us to criminal penalties, civil penalties, recall or seizure of products, withdrawal of marketing approval, total or partial suspension of production or injunction, as well as other regulatory actions against our product or us.

If we market products in a manner that violates health care fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal health care fraud and abuse laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include antikickback statutes and false claims statutes.

The federal health care program antikickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed health care programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from antikickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid.

Recently, several pharmaceutical and other health care companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid Rebates. The majority of states also have statutes or regulations similar to the federal antikickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

The federal Controlled Substances Act might impose significant restrictions, licensing and regulatory requirements on the manufacturing, distribution and dispensing of certain of our product candidates.

The federal Controlled Substances Act imposes significant restrictions, licensing and regulatory requirements on the manufacturing, distribution and dispensing of controlled substances. Therefore, we must determine whether the Drug Enforcement Administration ("DEA") would consider any of our product candidates to be a controlled substance. We believe that it is unlikely that any of our product candidates, other than those which may act on the central nervous system, may be subject to regulation as controlled substances.

Facilities that conduct research, manufacture or distribute controlled substances must be registered to perform these activities and have the recordkeeping, reporting security, control and accounting systems required by the DEA to prevent loss and diversion. Failure to maintain compliance, particularly as manifested in loss or diversion, can result in significant regulatory action, including civil, administrative or criminal penalties. In addition, individual state laws may also impose separate regulatory restrictions and requirements, including licenses, recordkeeping and reporting. We believe that it is unlikely that any of our product candidates, other than those which may act on the central nervous system, may be subject to regulation as controlled substances.

We are planning to develop products that contain alvimopan and an opioid. For products that contain alvimopan and an opioid, we would be required to comply with the restrictions, licensing and regulatory requirements relating to controlled substances.

We may not obtain FDA approval to conduct clinical trials that are necessary to satisfy regulatory requirements.

Clinical trials are subject to oversight by institutional review boards and the FDA and:

- must conform with the FDA's good clinical practice regulations;
- must meet requirements for institutional review board oversight;
- must meet requirements for informed consent;
- are subject to continuing FDA oversight; and
- may require large numbers of test subjects.

Before commencing clinical trials in humans, we must submit to the FDA an Investigational New Drug Application, or IND. The FDA may decide not to permit the clinical trial to go forward. In addition, we, or the FDA, may suspend ongoing clinical trials at any time if the subjects participating in the trials are exposed to unacceptable health risks, or if the FDA finds deficiencies in the IND application or the conduct of the trials.

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights; we may be sued by others for infringing their intellectual property.

Our commercial success will depend in part on obtaining patent protection on our products and their uses and successfully defending these patents against third party challenges. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. Accordingly, we cannot predict the breadth of claims allowed in our patents or those of our collaborators.

Others have filed and in the future are likely to file patent applications covering products and technologies that are similar, identical or competitive to ours, or important to our business. We cannot be certain that any

patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference proceedings before the United States Patent and Trademark Office.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that will prevent our product candidates from being marketed unless we can obtain a license to those proprietary rights. Any patent related legal action against our collaborators or us claiming damages and seeking to enjoin commercial activities relating to our products and processes could subject us to potential liability for damages and require our collaborators or us to obtain a license to continue to manufacture or market the affected products and processes. We cannot predict whether we or our collaborators would prevail in any of these actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. There has been, and we believe that there will continue to be, significant litigation in the industry regarding patent and other intellectual property rights. If we become involved in litigation, it could consume substantial managerial and financial resources.

We rely on trade secrets to protect technology in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators and consultants to enter into confidentiality agreements, we may not be able to protect adequately our trade secrets or other proprietary information. Our research collaborators and scientific advisors have rights to publish data and information in which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, our ability to receive patent protection or protect our proprietary information may be imperiled.

We are a party to various license agreements that give us rights to use specified technologies in our research and development processes. If we are not able to continue to license such technology on commercially reasonable terms, our product development and research may be delayed. In addition, we generally do not fully control the prosecution of patents relating to in-licensed technology, and accordingly are unable to exercise the same degree of control over this intellectual property as we exercise over our internally developed technology.

Our ability to generate revenues will be diminished if we fail to obtain acceptable prices or an adequate level of reimbursement for our products from third-party payors.

Our ability to commercialize pharmaceutical products, alone or with collaborators, may depend in part on the extent to which reimbursement for the products will be available from:

- government and health administration authorities; or
- private health insurers and third party payors.

The continuing efforts of government and third-party payors to contain or reduce the costs of health care through various means may limit our commercial opportunity. For example, in some foreign markets, pricing and profitability of prescription pharmaceuticals are subject to government control. In the United States, we expect that there will continue to be a number of federal and state proposals to implement pharmaceutical pricing and cost control measures under government health care programs such as Medicare and Medicaid. Increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Significant uncertainty exists as to the reimbursement status of newly approved health care products. Cost control initiatives could adversely affect our and our collaborator's ability to commercialize our products, decrease the price that any of our collaborators or we would receive for any products in the future, and may impede patients' ability to obtain reimbursement under their insurance programs for our products.

If we engage in an acquisition or business combination, we will incur a variety of risks that could adversely affect our business operations or our stockholders.

From time to time we have considered, and we will continue to consider in the future, if and when any appropriate opportunities become available, strategic business initiatives intended to further the development of our business. These initiatives may include acquiring businesses, technologies or products or entering into a business combination with another company. If we do pursue such a strategy, we could, among other things:

- issue equity securities that would dilute our current stockholders' percentage ownership;
- incur substantial debt that may place strains on our operations;
- spend substantial operational, financial and management resources in integrating new businesses, technologies and products;
- assume substantial actual or contingent liabilities; or
- merge with, or otherwise enter into a business combination with, another company in which our stockholders would receive cash or shares of the other company or a combination of both on terms that our stockholders may not deem desirable.

We are not in a position to predict what, if any, collaborations, alliances or other transactions may result or how, when or if these activities would have a material effect on us or the development of our business.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may have to limit or cease commercialization of our products.

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease commercialization of our products. We currently carry clinical trial insurance at a level we believe is commercially reasonable but do not carry product liability insurance. Our corporate collaborators or we may not be able to obtain insurance at a reasonable cost, if at all. There is no assurance that our clinical trial insurance will be adequate to cover claims that may arise.

We enter into various agreements where we indemnify third parties such as manufacturers and investigators for certain product liability claims related to our products. These indemnification obligations may cause us to pay significant sums of money for claims that are covered by these indemnifications.

If we use biological and hazardous materials in a manner that causes injury or violates laws, we may be liable for damages.

Our research and development activities involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals and various radioactive compounds. We use radioactivity in conducting biological assays and we use solvents that could be flammable in conducting our research and development activities. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials. We do not maintain a separate insurance policy for these types of risks. In the event of contamination or injury, we could be held liable for damages that result, and any liability could exceed our resources. We are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations could be significant.

Certain provisions of our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult.

Provisions of our amended and restated certificate of incorporation and restated by-laws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us, even if doing so would benefit our stockholders.

We have shares of our common stock and preferred stock available for future issuance without stockholder approval. The existence of unissued common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, which would protect the continuity of our management.

Our amended and restated certificate of incorporation provides for our board of directors to be divided into three classes, with the term of one such class expiring each year, and we have eliminated the ability of our stockholders to consent in writing to the taking of any action pursuant to Section 228 of the Delaware General Corporation Law.

In addition, we adopted a shareholder rights plan, the effect of which may be to make an acquisition of the Company more difficult.

Under our collaboration agreement with Glaxo, there are certain limitations on Glaxo's ability to acquire our securities. During and for one year after the term of the collaboration agreement, Glaxo and its affiliates will not, alone or with others, except as permitted under limited circumstances:

- acquire or agree to acquire, directly or indirectly, any direct or indirect beneficial ownership or interest in any of our securities or securities convertible into or exchangeable for any of our securities;
- make or participate in any solicitation of proxies to vote in connection with us;
- form, join or in any way participate in a group with respect to our voting securities;
- acquire or agree to acquire, directly or indirectly, any of our assets or rights to acquire our assets, unless we are selling those assets at that time; or
- otherwise seek to change the control of us or propose any matter to be voted on by our stockholders or nominate any person as a director of us who is not nominated by the then incumbent directors.

These limitations make it more difficult for Glaxo to acquire us, even if such an acquisition would benefit our stockholders. The limitations do not prevent Glaxo, among other things, from acquiring our securities in certain circumstances following initiation by a third party of an unsolicited tender offer to purchase more than a certain percentage of any class of our publicly traded securities.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We conduct operations in a building in Exton, Pennsylvania, under a ten-year lease agreement expiring in July 2013. The building has approximately 80,000 square feet of space. We have built out and occupy approximately 30,000 square feet of office space and approximately 25,000 square feet of laboratory space. The remaining approximately 25,000 square feet of space is unfinished and is available for potential future expansion.

ITEM 3. LEGAL PROCEEDINGS

On April 21, 2004, a lawsuit was filed in the United States District Court for the Eastern District of Pennsylvania against the Company, one of its directors and certain of its officers seeking unspecified damages on behalf of a putative class of persons who purchased our common stock between September 23, 2003 and January 14, 2004. The complaint alleges violations of Section 10(b) and Section 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), in connection with the announcement of the results of certain studies in the

Company's Phase III clinical trials for *Entereg*, which allegedly had the effect of artificially inflating the price of our common stock. This suit has been consolidated with three subsequent actions asserting similar claims under the caption: *In re Adolor Corporation Securities Litigation*, No. 2:04-cv-01728. On December 29, 2004, the district court issued an order appointing the Greater Pennsylvania Carpenters' Pension Fund as Lead Plaintiff. The appointed Lead Plaintiff filed a consolidated amended complaint on February 28, 2005. That Complaint purported to extend the class period, so as to bring claims on behalf of a putative class of Adolor shareholders who purchased stock between September 23, 2003 and December 22, 2004. The Complaint also adds as defendants our Board of Directors asserting claims against them and the other defendants for violation of Section 11 and Section 15 of the Securities Act of 1933 in connection with our public offering of stock in November 2003. The Company and the management and director defendants moved to dismiss the Complaint on April 29, 2005. The plaintiffs responded to the motion to dismiss on June 28, 2005, and the defendants' reply was filed on August 12, 2005. We believe that the allegations are without merit and intend to vigorously defend the litigation.

On August 2, 2004, two shareholder derivative lawsuits were filed in the United States District Court for the Eastern District of Pennsylvania, purportedly on behalf of the Company, against its directors and certain of its officers seeking unspecified damages for various alleged breaches of fiduciary duty and waste. The allegations are similar to those set forth in the class action complaints, involving the announcement of the results of certain studies in the Company's Phase III clinical trials for *Entereg*. On November 12, 2004, the Derivative Plaintiff filed an amended Complaint. On December 13, 2004, we filed a motion challenging the standing of the Derivative Plaintiff to file the derivative litigation on its behalf. On December 13, 2004, the Company's directors and officers moved to dismiss the Complaint for the failure to state a claim. Plaintiffs responded to the Company's and the directors' and officers' motions on January 27, 2005. The Company and the Directors and Officers filed reply briefs on February 18, 2005.

We have not accrued any amount in our Consolidated Financial Statements as of December 31, 2006 for these matters.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of our stockholders, through the solicitation of proxies or otherwise, during the fourth quarter of the fiscal year ended December 31, 2006.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

(a) *Market Information.* Our common stock is traded on The Nasdaq Stock Market LLC under the symbol "ADLR". The price range per share reflected in the table below is the highest and lowest per share sales price for our stock as reported by The Nasdaq Stock Market during each quarter of the two most recent years.

| | High | Low |
|----------------------|---------|---------|
| 2005 | | |
| First Quarter | \$10.93 | \$ 7.94 |
| Second Quarter | 10.49 | 8.57 |
| Third Quarter | 12.19 | 8.28 |
| Fourth Quarter | 15.88 | 9.12 |
| 2006 | | |
| First Quarter | \$27.80 | \$14.05 |
| Second Quarter | 25.17 | 21.30 |
| Third Quarter | 26.17 | 11.85 |
| Fourth Quarter | 15.51 | 7.13 |

(b) *Holders.* As of February 9, 2007, there were approximately 140 holders of record of our common stock. This does not reflect beneficial stockholders who hold their stock in nominee or "street" name through various brokerage firms.

(c) *Dividends.* We have never declared or paid cash dividends on our capital stock, and we do not intend to pay cash dividends in the foreseeable future. We plan to retain any earnings for use in the operation of our business and to fund future growth.

(d) *Securities Authorized for Issuance under Equity Compensation Plans.*

Equity Compensation Plan Information

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (a) | Weighted-average exercise price of outstanding options, warrants and rights (b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c) |
|---|---|---|---|
| Equity compensation plans approved by security holders (1) | 4,242,085 | \$13.82 | 3,145,637 |

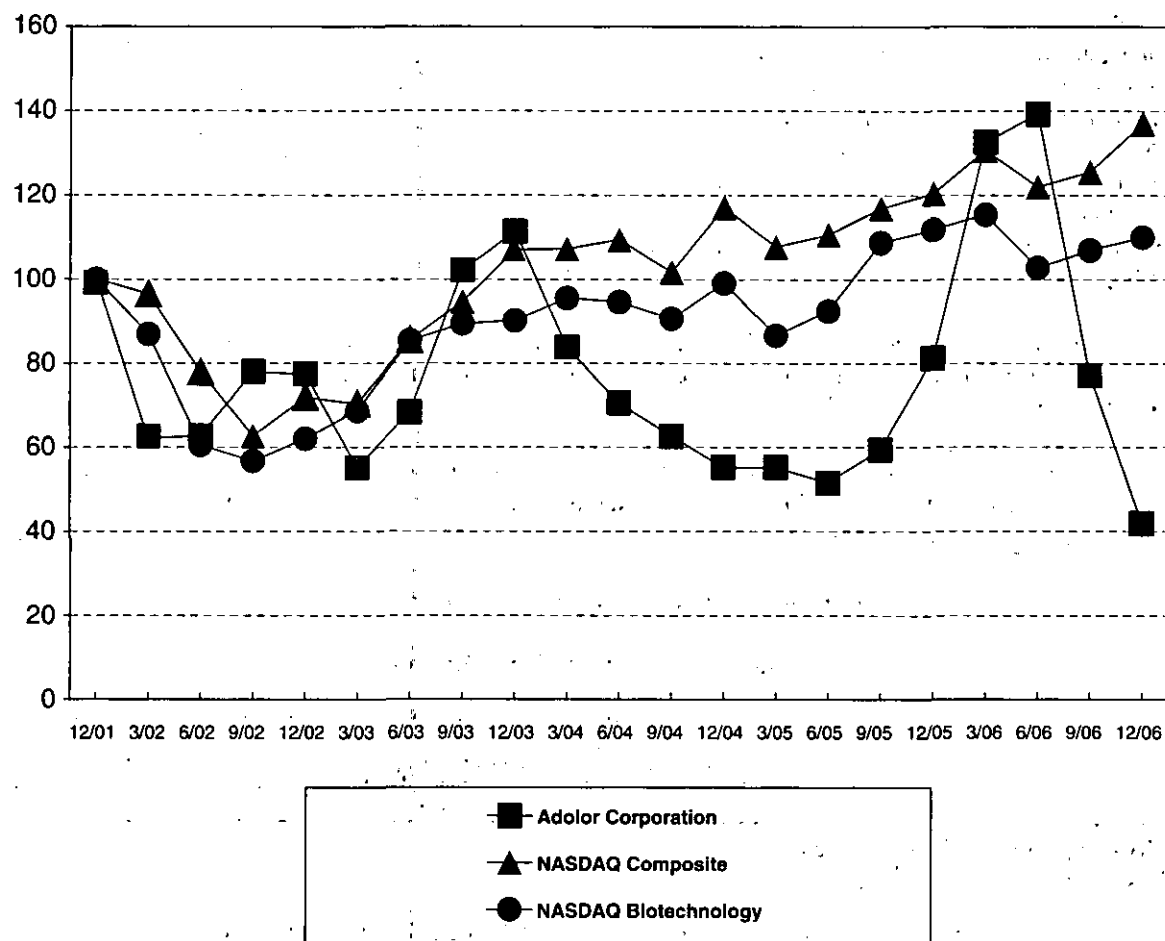
(1) Consists of options available for grant by us under our 2003 Stock-Based Incentive Compensation Plan and our Amended and Restated 1994 Equity Compensation Plan.

(e) Performance Graph

The following graph compares the cumulative 5-year total return provided stockholders on our common stock relative to the cumulative total returns of the NASDAQ Composite index and the NASDAQ Biotechnology index. An investment of \$100 (with reinvestment of all dividends) is assumed to have been made in our common stock and in each of the indexes on December 31, 2001 and its relative performance is tracked through December 31, 2006.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among Adolor Corporation, The NASDAQ Composite Index
And The NASDAQ Biotechnology Index



* \$100 invested on 12/31/01 in stock or index-including reinvestment of dividends.
Fiscal year ending December 31.

The stock price performance included in this graph is not necessarily indicative of future stock price performance.

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with our Consolidated Financial Statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report. The Consolidated Statements of Operations data for the years ended December 31, 2006, 2005, and 2004, and our Consolidated Balance Sheet data as of December 31, 2006 and 2005, are derived from our audited Consolidated Financial Statements which are included elsewhere in this Annual Report. The Consolidated Statements of Operations data for the years ended December 31, 2003 and 2002 and the Consolidated Balance Sheet data as of December 31, 2004, 2003 and 2002 are derived from audited Consolidated Financial Statements not included in this Annual Report. Historical results are not necessarily indicative of the results to be expected in the future.

Please see Note 2 to our Consolidated Financial Statements for an explanation of the method used to calculate the net loss allocable to common stockholders, net loss per share and the number of shares used in the computation of per share amounts.

| | Years Ended December 31, | | | | |
|--|---------------------------------------|--------------------|--------------------|--------------------|--------------------|
| | 2006 | 2005 | 2004 | 2003 | 2002 |
| | (In thousands, except per share data) | | | | |
| Consolidated Statements of Operations | | | | | |
| Contract revenues | \$ 15,087 | \$ 15,719 | \$ 25,542 | \$ 20,727 | \$ 28,409 |
| Operating expenses incurred during the development stage: | | | | | |
| Research and development | 56,660 | 49,631 | 48,766 | 56,654 | 71,705 |
| Marketing, general and administrative | 37,690 | 26,293 | 22,870 | 17,648 | 21,693 |
| Total operating expenses | 94,350 | 75,924 | 71,636 | 74,302 | 93,398 |
| Net other income | 9,524 | 3,408 | 2,508 | 2,369 | 4,465 |
| Net loss | <u>\$ (69,738)</u> | <u>\$ (56,797)</u> | <u>\$ (43,586)</u> | <u>\$ (51,206)</u> | <u>\$ (60,524)</u> |
| Basic and diluted net loss per share allocable to common stockholders | <u>\$ (1.56)</u> | <u>\$ (1.45)</u> | <u>\$ (1.12)</u> | <u>\$ (1.57)</u> | <u>\$ (1.94)</u> |
| Shares used in computing basic and diluted net loss per share allocable to common stockholders | <u>44,731</u> | <u>39,088</u> | <u>38,924</u> | <u>32,586</u> | <u>31,252</u> |
| | As of December 31, | | | | |
| | 2006 | 2005 | 2004 | 2003 | 2002 |
| | (In thousands) | | | | |
| Consolidated Balance Sheet Data | | | | | |
| Cash, cash equivalents and short-term investments | \$ 185,562 | \$ 103,075 | \$ 162,324 | \$ 210,174 | \$ 153,985 |
| Working capital | 173,130 | 89,664 | 149,081 | 195,531 | 140,290 |
| Total assets | 200,598 | 117,237 | 178,103 | 224,664 | 168,271 |
| Deficit accumulated during the development stage | (376,502) | (306,763) | (249,967) | (206,380) | (155,174) |
| Total stockholders' equity | 153,181 | 66,693 | 123,160 | 165,279 | 100,728 |

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a development stage biopharmaceutical corporation that was formed in 1993. Since inception, we have specialized in the discovery and development of prescription pain management products and expect to commercialize products that are successfully developed. We have a number of product candidates in various stages of development, ranging from preclinical studies to pivotal clinical trials. Our most advanced product candidate, *Entereg*® (alvimopan), is intended to selectively block the unwanted effects of opioid analgesics on the gastrointestinal (GI) tract. For the global development and commercialization of *Entereg* as a monotherapy, we are collaborating with Glaxo Group Limited (Glaxo) in multiple indications. Separately, we are also developing products that combine alvimopan with an opioid analgesic. In addition to products based on alvimopan, we are developing a delta opioid agonist which is currently in phase I clinical safety testing. Additional product candidates are in preclinical development for the treatment of moderate-to-severe pain conditions.

Entereg® (alvimopan)

Opioid analgesics provide pain relief by stimulating opioid receptors located in the central nervous system. There are, however, opioid receptors throughout the body, including the GI tract. By binding to the receptors in the GI tract, opioid analgesics can slow gut motility and disrupt normal GI function that allows for the passage, absorption and excretion of ingested solid materials. This disruption can cause patients to experience significant discomfort and abdominal pain and may result in their reducing or eliminating their pain medication.

Entereg is a small molecule, *mu*-opioid receptor antagonist intended to block the adverse side effects of opioid analgesics on the GI tract without affecting analgesia. We are developing *Entereg* for both acute and chronic conditions. The acute indication currently under development is the management of postoperative ileus (POI), a GI condition characterized by the slow return of gut function that can result from GI or other surgeries. *Entereg* is also being developed to treat opioid-induced bowel dysfunction (OBD), which is a condition characterized by a number of GI symptoms, including constipation, that often results from chronic use of opioid analgesics to treat persistent pain conditions.

In April 2002, we entered into a collaboration agreement with Glaxo for the exclusive worldwide development and commercialization of *Entereg* for certain indications. We are responsible for development of acute indications, such as POI, and Glaxo is responsible for development of chronic indications, such as OBD. In the United States, we and Glaxo are co-developing *Entereg* and intend to share profits that result from the sale of the product. For commercial sales of *Entereg* for POI in the United States, we would receive 45% and Glaxo would receive 55% of the net sales less certain agreed upon costs, and subject to certain adjustments. After the first three years each party's share would become 50%. For commercial sales of *Entereg* for OBD in the United States, we would receive 35% and Glaxo would receive 65% of the net sales less certain agreed upon costs, and subject to certain adjustments. Under the collaboration agreement, we have the right to convert our right to receive a profit share for OBD in the United States to a royalty on net sales of 20%. Outside the United States, Glaxo is responsible for the development and commercialization of *Entereg*, and we would receive royalties on net sales. We may receive additional milestone payments under the collaboration agreement upon the successful achievement, if any, of certain clinical and regulatory objectives, including up to \$40 million related to the POI indication and up to \$25 million related to the OBD indication.

POI Development Program

Regulatory Overview

We have invested a significant portion of our time and financial resources since our inception in the development of *Entereg*, and our potential to achieve revenues from product sales in the foreseeable future is dependent largely upon obtaining regulatory approval for and successfully commercializing *Entereg*, especially in the United States. We have completed four Phase III clinical studies of *Entereg* for the management of

POI, and submitted a New Drug Application (NDA) for *Entereg* 12 mg capsules to the Food and Drug Administration (FDA) in June 2004. Additionally, Glaxo has completed a Phase III study evaluating *Entereg* in POI conducted in Europe, Australia and New Zealand (Study 001). Our NDA was amended in April 2005 to include data from Study 001.

In November 2006, we announced the receipt of our second approvable letter from the FDA for *Entereg* 12 mg capsules, under review for the management of POI by acceleration of GI function following bowel resection surgery. An approvable letter is a letter from the FDA to an NDA applicant indicating that the FDA may approve the NDA if specific additional information is submitted or specific conditions are agreed upon. The November 2006 approvable letter indicated that before the application for *Entereg* may be approved, it will be necessary to provide the twelve-month safety data, including analysis of serious cardiovascular events from study 767905/014 (Study 014), an ongoing safety study being conducted by Glaxo in OBD. The FDA's review of the NDA for POI included a six-month interim analysis of Study 014. The Study 014 interim analysis showed an increase, which was not statistically significant, in the reported incidence of serious cardiovascular adverse events in patients receiving alvimopan as compared to patients receiving placebo. The FDA also requested a risk management plan.

On December 14, 2006, we announced that we were disbanding our sales force of approximately 35 people and made other select reductions to our workforce due to receipt of our second approvable letter from the FDA.

Glaxo has recently completed last patient last visit for Study 014, with top-line results expected to be available by the second quarter of 2007. We expect to submit Study 014 data, along with a proposed risk management plan, in a complete response to the November 2006 approvable letter in the second quarter of 2007.

In July 2005, we received our first approvable letter from the FDA. The July 2005 approvable letter indicated that before the application for *Entereg* may be approved, it will be necessary to provide additional proof of efficacy to the FDA to support the use of *Entereg* following bowel resection surgery. The FDA indicated that this may be achieved by demonstrating statistically significant results in at least one additional clinical study, and that this could potentially be addressed with positive results from our Study 14CL314 (Study 314). Results from Study 314 were announced in February 2006. The FDA also indicated that we must provide justification that the median reduction in time to gastrointestinal recovery seen in bowel resection patients treated with *Entereg* is clinically meaningful. Following completion of Study 314, we submitted a complete response to the July 2005 NDA approvable letter. The FDA issued the November 2006 NDA approvable letter at the conclusion of its review.

Clinical Overview

Our *Entereg* POI Phase III clinical program in support of the NDA submitted in June 2004 included four studies. Three of these studies (POI 14CL302, POI 14CL308 and POI 14CL313) were double-blind, placebo-controlled multi-center studies, each designed to enroll patients scheduled to undergo certain types of major abdominal surgery and receiving opioids for pain relief. Under the protocols, patients were randomized into three arms to receive placebo, 6 mg or 12 mg doses of *Entereg*. The primary endpoint in these three efficacy studies was time to recovery of GI function (GI3), a composite measure of the time to recovery of both upper and lower GI function, as defined by time to tolerability of solid foods, and time to first flatus or first bowel movement, whichever occurred last. The fourth POI clinical study in our Phase III program, POI 14CL306, was a double-blind, placebo-controlled multi-center observational safety study under which patients were randomized to receive either *Entereg* 12 mg (413 patients) or placebo (106 patients). GI3 was included as one of the secondary endpoints in the study. Glaxo also completed a Phase III study, Study 001, evaluating *Entereg* in POI.

We have also conducted an additional study in support of our pending NDA, Study 314. The protocol for Study 314 provides that the initial dose of *Entereg* should be administered 30 to 90 minutes prior to surgery, as compared to our previous Phase III studies where the first dose was required to be administered (at least) 120 minutes prior to surgery. The primary endpoint of Study 314 is time to recovery of GI function, GI2, a composite measure of the time to recovery of both upper and lower GI function, as defined by time to tolerability of solid foods, and time to first bowel movement, whichever occurred last. Study 314 was designed to evaluate certain secondary endpoints.

Study 302. In April 2003, we announced top-line results of our first POI Phase III clinical study, POI 14CL302. Study POI 14CL302 enrolled 451 patients and was designed to include large bowel resection patients and radical hysterectomy patients, as well as simple hysterectomy patients (22% of enrolled patients). A statistically significant difference was achieved in the primary endpoint of the study in patients in the *Entereg* 6 mg treatment group compared to patients in the placebo group (Cox proportional hazard model, hazard ratio = 1.45; $P < 0.01$). A positive trend was observed in the primary endpoint of the study for the *Entereg* 12 mg treatment group; however, the difference from placebo was not statistically significant (Cox proportional hazard model, hazard ratio = 1.28; $P = 0.059$). A difference in favor of the *Entereg* treatment groups versus placebo was observed for all secondary endpoints, including time to hospital discharge order written. The most frequently observed adverse events in both the placebo and treatment groups were nausea, vomiting and abdominal distension.

The hazard ratio measures the degree of difference between the study drug group and the placebo group. A hazard ratio of 1 would indicate no difference between the study drug group and the placebo group in the probability of achieving the endpoint. A hazard ratio of 1.5 means that subjects receiving drug are 50% more likely to achieve the endpoint, on average, during the course of the data collection period. Statistical analyses estimate the probability that an effect is produced by the drug. This probability is generally expressed as a "P value" which is an estimate of the probability that any difference measured between the drug group and the placebo group occurred by chance. For example, when a P value is reported as $P < 0.05$, the probability that the study demonstrated a drug effect by chance is less than 5%.

Study 313. In September 2003, we announced top-line results of our second POI Phase III clinical study, POI 14CL313. Study POI 14CL313 enrolled 510 patients and was designed to include large bowel resection patients, small bowel resection patients and radical hysterectomy patients, and exclude simple hysterectomy patients. A statistically significant difference was achieved in the primary endpoint of the study, time to recovery of GI function, in both the *Entereg* 6 mg and 12 mg treatment groups compared to the placebo group (Cox proportional hazard model; for 6 mg group, hazard ratio = 1.28; $P < 0.05$; for 12 mg group, hazard ratio = 1.54; $P < 0.01$). A difference in favor of *Entereg* was observed for all of the secondary endpoints in both the 6 mg and 12 mg treatment groups, including time to hospital discharge order written. The most frequently observed adverse events in both the placebo and treatment groups were nausea, vomiting and hypotension.

Study 306. In October 2003, we announced top-line results of our third POI Phase III clinical study, POI 14CL306, which enrolled 519 patients. This study was designed to assess safety as its primary endpoint, and to assess efficacy as a secondary endpoint and to enroll only patients scheduled to undergo simple hysterectomy procedures. Study POI 14CL306 was the first study where dosing continued on an out-patient basis after patients were discharged from the hospital. *Entereg* was generally well tolerated in this observational safety study with 93% of patients completing treatment in the *Entereg* 12 mg treatment group and 92% of patients completing treatment in the placebo group. The most frequently observed adverse events in both the placebo and treatment groups were nausea, vomiting and constipation. The results in GI3, one of the secondary endpoints in the study, were not statistically significant as compared to placebo.

Study 308. In January 2004, we announced top-line results of our fourth POI Phase III clinical study, POI 14CL308. Study POI 14CL308 enrolled 666 patients, and was designed to include large bowel resection patients, small bowel resection patients and radical hysterectomy patients, as well as simple hysterectomy patients (14% of enrolled patients). A positive trend was observed in the primary endpoint of the study when each of the *Entereg* 6 mg and 12 mg treatment groups was compared to the placebo group (Cox proportional hazard model; for 6 mg group, hazard ratio = 1.20, $P = 0.08$; for 12 mg group, hazard ratio = 1.24, $P = 0.038$). Due to the multiple dose comparison to a single placebo group, a P-value of less than 0.025 would have been required in the 12 mg dose group to be considered statistically significant. A difference in favor of *Entereg* was observed for all of the secondary endpoints in both the 6 mg and 12 mg treatment groups, including time to hospital discharge order written. The most frequently observed adverse events in both the placebo and treatment groups were nausea, vomiting and pruritis.

Study 001. In December 2004, we reported top-line results from a Phase III clinical study of *Entereg* in POI, Study 001. Study 001 was conducted in Europe, Australia and New Zealand by Glaxo and enrolled 741 bowel resection patients, and 170 radical hysterectomy patients. The prespecified primary analysis group only included the bowel resection patients. The primary endpoint results (GI3) of the study were (Cox proportional hazard model) for the 6 mg group, hazard ratio = 1.22 (P=0.042); and for the 12 mg group, hazard ratio = 1.13 (P=0.20), each as compared to placebo. These results are not statistically significant; due to the multiple dose comparison to a single placebo group, a P-value of less than 0.025 would be required in the 6 mg dose group to be considered statistically significant. The most frequently observed adverse events were nausea, vomiting and pyrexia.

Study 314. In February 2006, we announced top-line results of our Phase III clinical study, POI 14CL314, which enrolled 654 patients scheduled to undergo large or small bowel resection. For the primary GI2 endpoint of Study 314, a statistically significant difference was achieved as compared to placebo (Cox proportional hazard model) hazard ratio = 1.53, P<0.001. A statistically significant difference in favor of *Entereg* was achieved for each of the secondary time to event endpoints. Under the protocol, patients were randomized to receive placebo or 12 mg of *Entereg* twice daily. While GI3 was the primary endpoint for pivotal studies in our NDA, GI2 has been measured in each study. The data for the effect on time to GI2 recovery for bowel resection patients (MITT population) for the 12 mg dose of *Entereg* as an additional analysis is as follows: in Study 302, the hazard ratio was 1.400 and the P-value 0.029; in Study 308, the hazard ratio was 1.365 and the P-value 0.017; in Study 313, the hazard ratio was 1.625 and the P-value <0.001; and in Study 001, the hazard ratio was 1.299 and the P-value 0.008. The most frequently observed adverse events were nausea, vomiting and abdominal distension.

OBD Clinical Development Program

Entereg is being developed by Glaxo for the treatment of OBD in patients taking opioid analgesics for persistent pain conditions. In September 2006, we and Glaxo announced the top-line results from two Phase III registration studies, Studies SB-767905/012 (Study 012) and SB-767905/013 (Study 013) of alvimopan for the treatment of OBD in patients with chronic non-cancer pain, and one Phase 2b study, Study 767905/008 (Study 008) in patients with chronic cancer pain taking opioids and experiencing symptoms associated with OBD. Additionally, Glaxo recently completed last patient last visit for a Phase III long-term safety study, Study 014, and top-line results from this study are expected to be available by the second quarter of 2007.

Glaxo and we are currently planning potential next steps in the development of *Entereg* for OBD.

Study 012. In September 2006, we and Glaxo announced top-line results from a Phase III clinical study of *Entereg* in OBD, Study 012, a randomized, double-blind, placebo-controlled, multi-center study under which patients were randomized to one of two *Entereg* arms (0.5 mg once daily or 0.5 mg twice daily) or to placebo for twelve weeks of treatment. Study 012 enrolled 518 patients with chronic non-cancer pain who had experienced symptoms of OBD, defined as having less than 3 SBMs (defined as bowel movements with no laxative in the previous 24 hours) a week plus one or more bowel movement symptoms (incomplete evacuation, straining, hard/small pellets) for 25% of bowel movements. This study achieved statistical significance for the primary endpoint, the proportion of patients who had a weekly average of three or more SBMs and an increase from baseline of one or more SBMs a week over the 12-week treatment period. In patients treated with alvimopan 0.5 mg twice daily, 72% met the primary endpoint compared with 48% of patients receiving placebo (p less than 0.001). In patients treated with alvimopan 0.5 mg once daily, 61% met the primary endpoint compared with 48% of patients receiving placebo (p=0.065).

Study 013. In September 2006, we and Glaxo also announced top-line results from a Phase III clinical study of *Entereg* in OBD, Study 013, a randomized, double-blind, placebo-controlled, multi-center study under which patients were randomized to one of two *Entereg* arms (0.5 mg once daily or 0.5 mg twice daily) or to placebo for twelve weeks of treatment. Study 013 enrolled 485 patients with chronic non-cancer pain and its enrollment criteria and endpoints were identical to Study 012. In both groups of patients treated with alvimopan,

0.5 mg twice and once daily, over the 12-week treatment period, 63% met the primary endpoint, compared with 56% of patients receiving placebo ($p=0.214$ and $p=0.259$ respectively). These results are not statistically significant.

Entereg was generally well tolerated in Studies 012 and 013. Adverse events affecting the gastrointestinal (GI) tract were the most common in both studies occurring in 24-33% of alvimopan-treated patients, compared with 22% on placebo. These included abdominal pain, diarrhea, nausea and vomiting.

Study 008. In September 2006, we and Glaxo also announced top-line results from a Phase 2b clinical study of *Entereg* in patients with chronic cancer pain taking opioids and experiencing symptoms associated with OBD, Study 008. Study 008 enrolled 233 patients. The primary endpoint in this study was the change in frequency of spontaneous complete bowel movements (SCBMs), defined as a bowel movement with no laxative use in the previous 24 hours that provides the subject with a feeling of complete evacuation. The average weekly change from baseline for the three week treatment period was 1.9, 1.8 and 2.1 SCBMs for patients treated with alvimopan 0.5 mg twice daily, 1.0 mg once and twice daily, respectively, compared to 1.6 SCBMs in those receiving placebo. These differences were not statistically significant. The safety and tolerability of *Entereg* in this cancer pain study were similar to that seen in the placebo group.

Study 014. Study 014, is a randomized, double-blind, placebo-controlled study designed to enroll approximately 750 adults who are taking opioid therapy for persistent non-cancer pain and have OBD. Under the protocol, the patients are randomized to *Entereg* (0.5 mg twice daily) or placebo for twelve months of treatment. The primary objective of this Phase III long-term safety study is to compare *Entereg* with placebo for safety and tolerability in the treatment of OBD. The primary safety endpoint is based on the frequency of reported adverse events. A six month interim analysis of Study 014 was submitted to the FDA in September 2006 in connection with the FDA's review of our NDA for POI. This analysis showed an increase, which was not statistically significant, in the reported incidence of serious cardiovascular adverse events in patients receiving *Entereg* as compared to patients receiving placebo.

Glaxo has recently completed last patient last visit for study 014, with top-line results expected to be available by the second quarter of 2007. We expect to submit Study 014 data, along with a proposed risk management plan, in a complete response to the November 2006 approvable letter in the second quarter of 2007.

Study SB767905/011 (Study 011). In March 2005, we and Glaxo announced top-line results from a Phase IIb study of *Entereg* in OBD. In Study 011, in 522 non-cancer patients with OBD, all three oral *Entereg* dosage regimens achieved statistically significant effects on the primary and secondary endpoints compared with placebo. The primary endpoint was the change from baseline in weekly frequency of SBMs over the first half of the 6-week treatment period. All groups reported an SBM frequency of approximately 1 per week during the baseline period. The average weekly change from baseline over weeks 1-3 was 3.36 SBM for the *Entereg* 0.5 mg, twice daily treatment group, 3.29 SBM for the *Entereg* 1mg, once daily treatment group and 4.17 SBM for the *Entereg* 1 mg, twice daily treatment group compared to 1.65 SBM for the placebo group. All *Entereg* treatment groups were statistically significantly different from placebo at the $P<0.001$ level. In this Phase IIb study adverse events affecting the GI tract were the most common, occurring in 30%-43% of *Entereg* treated patients, compared to 36% on placebo. The most frequently reported adverse events were abdominal pain, nausea and diarrhea and GI adverse events were also the most common reason for study withdrawal.

Combination Product

We are developing an analgesic product candidate that combines alvimopan and an opioid analgesic. This combination is intended to produce the pain relief of an opioid while reducing constipating side effects. During the second quarter of 2006 we commenced a Phase II dose ranging study in which alvimopan is co-administered with hydrocodone/APAP. This study is designed to enroll up to 300 patients undergoing ambulatory shoulder surgery for rotator cuff repair.

We also filed an Investigational New Drug Application (IND) for a coformulated hydrocodone/APAP and alvimopan product and have completed a phase I pharmacokinetic study which showed comparable drug levels in the co-formulated product and co-administered products.

Sterile Patch Program (ADL 8-7223)

We have determined not to continue pursuing development of our sterile lidocaine patch program. As a result, on October 27, 2006, we provided notice to EpiCept Corporation that we were terminating our License Agreement dated July 23, 2003, under which we licensed exclusive rights to develop and commercialize in North America a sterile lidocaine patch. Also as a result, on October 27, 2006, we provided notice to Corium International, Inc. that we were terminating our Scale Up and Commercial Supply Agreement dated November 16, 2005.

Delta Agonist Program

Through a proprietary research platform based on cloned, human opioid receptors, we have identified a series of novel, orally active *delta* agonists that selectively stimulate the *delta* opioid receptor. The *delta* receptor is one of three opioid receptors that modulate pain; the other receptors being the *mu* and *kappa* receptors. Today, all marketed opioid drugs interact with the *mu* receptors in the brain and spinal cord.

On the basis of preclinical evaluation in animal models of human conditions, one might expect a *delta* agonist to show effect in inflammatory pain, among other pain conditions. In addition, *delta* agonists are thought to modulate other biological processes that may manifest themselves in disease states or conditions such as overactive bladder and depression.

We are conducting Phase I clinical testing of our lead *delta* compound, ADL5859. During the third quarter of 2006, we commenced a Phase I clinical trial of ADL5859 designed to investigate the safety, tolerability and pharmacokinetics of a single dose of ADL5859 in healthy volunteers. We completed this single dose study in the fourth quarter of 2006 and are now conducting a multi-dose Phase I clinical study.

Discovery / In-Licensing

Our pain research efforts initially focused on designing small molecules to target peripheral opioid receptors as a means of avoiding the centrally mediated side effects of currently available opioid analgesics. While work continues on the selective targeting of peripheral opioid receptors, new research is using advancements in molecular biology and medicinal chemistry to design molecules to avoid prototypical opioid receptor-induced side effects. In addition, our discovery research team is actively assessing other, non-opioid pain targets. The overall goal of these programs is to develop medications that produce pain relief equal to or superior to traditional narcotics, while reducing or eliminating typical narcotic side effects.

We believe there are opportunities to expand our product portfolio through the acquisition or in-licensing of products and/or product development candidates and intend to continue to explore and evaluate such opportunities.

Competitive Environment

We operate in a highly regulated and competitive environment. Our competitors include fully integrated pharmaceutical companies and biotechnology companies, universities and public and private research institutions. Many of the organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals, and greater manufacturing and marketing capabilities than we do.

Commercialization

We intend to maintain a strategic marketing group to support our research and development efforts and commercial activities. We do not currently maintain a sales force to sell any products we may develop. We had previously built a 35-person sales force intended to sell *Entereg* in the hospital market, but disbanded this sales force in December 2006.

In our collaboration agreement with Glaxo, for the POI indication for *Entereg*, we are required to provide a limited number of full-time equivalent sales personnel to sell the product. Under that agreement, we may request that Glaxo perform such sales effort, at our expense. If Glaxo does not choose to do so, we may engage a contract sales organization to provide such services. The discontinuation of our sales force does not affect the profit sharing arrangement in our collaboration agreement with Glaxo.

We have a small manufacturing organization to manage our relationships with third parties for the manufacture and supply of products for preclinical, clinical and commercial purposes. We maintain commercial supply agreements with certain of these third party manufacturers. We presently do not maintain our own manufacturing facilities.

In June 2004, we entered into a distribution agreement with Glaxo under which, upon our receipt of regulatory approvals, Glaxo will perform certain distribution and contracting services for *Entereg* on our behalf for a fee. Outside the United States, we intend to rely on Glaxo for sales and marketing of *Entereg* and expect to supply Glaxo with bulk capsules for commercial sale for POI under a supply agreement we entered into with Glaxo in September 2004.

As we develop additional product candidates we may enter into strategic marketing or co-promotion agreements with, and grant additional licenses to, pharmaceutical companies to gain access to additional markets both domestically and internationally.

Collaboration and Other Agreements With Glaxo

In April 2002, we entered into a collaboration agreement with Glaxo for the exclusive worldwide development and commercialization of *Entereg* for certain indications. Under the terms of the collaboration agreement, Glaxo paid us a non-refundable and non-creditable signing fee of \$50.0 million during the quarter ended June 30, 2002. Additionally, in the third quarter of 2004, we recognized \$10.0 million in revenue under this agreement relating to achieving the milestone of acceptance for review of our NDA by the FDA. We may receive additional milestone payments under the collaboration agreement upon the successful achievement, if any, of certain clinical and regulatory objectives including up to \$40 million related to the POI indication and up to \$25 million related to the chronic OBD indication. The milestone payments relate to substantive achievements in the development lifecycle and it is anticipated that these will be recognized as revenue if and when the milestones are achieved.

We and Glaxo have agreed to develop *Entereg* for a number of acute and chronic indications which would potentially involve the use of *Entereg* in in-patient and out-patient settings. In the United States, we and Glaxo are co-developing and intend to share profits that result from the sale of product. For commercial sales of *Entereg* for POI in the United States, we would receive 45% and Glaxo would receive 55% of the net sales less certain agreed upon costs, and subject to certain adjustments. After the first three years each party's share would become 50%. For commercial sales of *Entereg* for OBD in the United States, we would receive 35% and Glaxo would receive 65% of the net sales less certain agreed upon costs, and subject to certain adjustments. Under the collaboration agreement, we have the right to convert our right to receive a profit share for OBD in the United States to a royalty on net sales of 20%. We have overall responsibility for development activities for acute care indications such as POI, and Glaxo has overall responsibility for development activities for chronic care indications such as OBD. Outside the United States, Glaxo is responsible for the development and commercialization of *Entereg* for all indications, and we would receive royalties on net sales, if any.

The term of the collaboration agreement varies depending on the indication and the territory. The term of the collaboration agreement for the POI indication in the United States is ten years from the first commercial sale of *Entereg* in that indication, if any. Generally, the term for the OBD indication in the United States is fifteen years from the first commercial sale of *Entereg* in that indication, if any. In the rest of the world, the term is generally fifteen years from the first commercial sale of *Entereg*, if any, on a country-by-country and indication-by-indication basis.

Glaxo has certain rights to terminate the collaboration agreement. Glaxo also has the right to terminate its rights and obligations with respect to the acute-care indications, or its rights and obligations for the chronic-care indications. Glaxo has the right to terminate the collaboration agreement for breach of the agreement by us or for safety related reasons as defined in the collaboration agreement. Glaxo's rights to terminate the acute-care indications or the chronic-care indications are generally triggered by failure to achieve certain milestones within certain timeframes, adverse product developments or adverse regulatory events. For example, because the POI product has not been commercially sold as of December 31, 2005, Glaxo now possesses the right to terminate the collaboration agreement with respect to the POI product and the OBD chronic product.

In June 2004, we entered into a distribution agreement with Glaxo under which, upon our receipt of regulatory approvals, Glaxo will perform certain distribution and contracting services for *Entereg* on our behalf for a fee. Outside of the United States we intend to rely on Glaxo for sales and marketing of *Entereg*, and expect to supply Glaxo with bulk capsules for sale under a supply agreement we entered into with Glaxo in September 2004.

External expenses for research and development and marketing activities incurred by each company in the United States are reimbursed by the other party pursuant to contractually agreed percentages. Contract reimbursement amounts owed to us by Glaxo are recorded gross on our Consolidated Statements of Operations as cost reimbursement under collaborative agreement revenue. Amounts reimbursable to Glaxo by us are recorded as research and development or marketing expense, as appropriate, on our Consolidated Statements of Operations.

License Agreements

In November 1996, Roberts licensed from Eli Lilly certain intellectual property rights relating to *Entereg*. In June 1998, we entered into an option and license agreement with Roberts under which we licensed from Roberts the rights Roberts had licensed from Eli Lilly for *Entereg*. We have made license and milestone payments under this agreement totaling \$1.6 million. If *Entereg* receives regulatory approval, we are obligated to make a milestone payment of \$900,000 under this agreement, as well as royalties on commercial sales of *Entereg*. Our license to *Entereg* expires on the later of either the life of the last to expire of the licensed Eli Lilly patents or fifteen years from November 5, 1996, following which we will have a fully paid up license.

In August 2002, we entered into a separate license agreement with Eli Lilly under which we obtained an exclusive license to six issued U.S. patents and related foreign equivalents and know-how relating to peripherally selective opioid antagonists. We paid Eli Lilly \$4.0 million upon signing the agreement and are subject to additional clinical and regulatory milestone payments and royalty payments to Eli Lilly on sales, if any, of new products utilizing the licensed technology. Under this license agreement, we also agreed to pay Eli Lilly \$4.0 million upon acceptance for review of our NDA by the FDA, which payment was made in the third quarter of 2004.

We are a party to various license agreements that give us rights to use technologies and biological materials in our research and development processes. We may not be able to maintain such rights on commercially reasonable terms, if at all. Failure by us or our licensors to maintain such rights could harm our business.

Critical Accounting Policies and Estimates

The preparation of our Consolidated Financial Statements in conformity with U. S. generally accepted accounting principles requires management to adopt critical accounting policies and to make estimates and assumptions that affect the amounts reported in our Consolidated Financial Statements and accompanying notes. These critical accounting policies and estimates have been reviewed by our audit committee. The principal items in our Consolidated Financial Statements reflecting critical accounting policies or requiring significant estimates and judgments are as follows:

Equity-based Compensation—Beginning on January 1, 2006, we account for our employee stock option grants under the provisions of SFAS No. 123R, *Share-Based Payments* ("SFAS 123R"). SFAS 123R requires the recognition of the fair value of equity-based compensation in the statement of operations. The fair value of our stock option awards was estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions and elections in adopting and implementing SFAS 123R, including expected stock price volatility and the estimated life of each award. The fair value of equity-based awards is amortized over the vesting period of the award and we have elected to use the straight-line method for awards granted after the adoption of SFAS 123R. Prior to the adoption of SFAS 123R, we accounted for our stock option grants under the provisions of Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB25") and made pro forma footnote disclosures as required by SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure, which amends SFAS No. 123, Accounting for Stock-Based Compensation*. Pro forma net income and pro forma net income per share for 2005 and 2004 are disclosed in the footnotes to our consolidated financial statements were estimated using a Black-Scholes option valuation model.

Collaborative Agreement Revenues—We record deferred revenue for amounts received upfront under collaboration agreements in which we have continuing involvement, and we recognize such deferred amounts as revenue ratably over the estimated contract performance period. Such revenue recognition may be accelerated in the event of contract termination prior to completion of the expected performance period or lengthened if the development period exceeds the initial estimate. Based on the receipt in November 2006 of the second approvable letter from the FDA, management has revised the expected performance period and will extend the period by two years. Under the terms of the collaboration agreement with Glaxo, we received a non-refundable and non-creditable upfront fee of \$50.0 million and, in 2006, approximately \$4.2 million of the \$50.0 million up-front fee was recognized as revenue. We expect to recognize the remaining deferred revenue through 2016, the revised estimated contract performance period.

Milestone fees are recorded as revenue when the milestone event is achieved.

Amounts reimbursable for costs incurred pursuant to the terms of collaboration agreements are recognized as revenue in the period in which the reimbursable costs are incurred. Such revenues are based on estimates of the reimbursable amount and are subject to verification by the collaborators. Accounts receivable from Glaxo of approximately \$2.8 million at December 31, 2006 is related to estimated reimbursable expenses for the fourth quarter of 2006, and is subject to verification by Glaxo.

Research and Development Expenses—We have entered into contracts with third parties to conduct certain research and development activities including pre-clinical, clinical and manufacturing development activities. We accrue expenses related to such contracts based upon an estimate of the amounts due for work completed under the contracts. Factors considered in preparing such estimates include the number of subjects enrolled in studies, materials produced by our manufacturers and other criteria relating to the progress of efforts by our vendors.

Liquidity and Capital Resources

We have experienced negative operating cash flows since our inception and have funded our operations primarily from the proceeds received from the sale of our equity securities, as well as contract revenues. Cash, cash equivalents and short-term investments were approximately \$185.6 million at December 31, 2006, and approximately \$103.1 million at December 31, 2005, representing 92.5% and 87.9% of our total assets, respectively. We invest excess cash in investment-grade fixed income securities, principally United States Treasury obligations. The increase in cash, cash equivalents and short-term investments was primarily the result

of our public offering of 5,750,000 shares of common stock at \$25.00 per share in February 2006. We received net proceeds from the offering of approximately \$135.1 million. This increase was partially offset by cash used in operating activities of \$63.8 million.

We believe that our current cash, cash equivalents and short-term investments are adequate to fund operations into 2009 based upon our expectations of the level of research and development, marketing and administrative activities necessary to achieve our strategic objectives.

The following is a summary of selected cash flow information for the twelve months ended December 31, 2006 and 2005:

| | Twelve Months Ended December 31, | |
|---|-------------------------------------|----------------|
| | 2006 | 2005 |
| Net loss | \$ (69,738,378) | \$(56,796,630) |
| Adjustments for non-cash operating items | 11,149,477 | 2,685,813 |
| Net cash operating loss | (58,588,901) | (54,110,817) |
| Net change in assets and liabilities | (5,253,904) | (4,357,600) |
| Net cash used in operating activities | (63,842,805) | (58,468,417) |
| Net cash (used in) provided by investing activities | (82,064,044) | 53,116,295 |
| Net cash provided by financing activities | 147,456,608 | 145,804 |

Net Cash Used In Operating Activities and Operating Cash Flow Requirements Outlook

Our operating cash outflows for 2006 and 2005 have resulted primarily from research and development expenditures associated with our product candidates, including clinical development and manufacturing costs for *Entereg*, compensation costs, as well as marketing, general and administrative expenses. These outflows were partially offset by cost reimbursement and milestone payments received from Glaxo and interest income earned on our investments.

We expect to continue to use cash resources to fund operating losses. We expect to continue to incur operating losses in 2007 and beyond due to continuing research and development expenses relating to *Entereg* and increased spending relating to other product development programs, including the combination product program and the delta programs. We also expect to incur marketing costs in preparation for the potential commercialization of *Entereg*, however, sales related costs in future periods will be reduced due to the reduction in force instituted in December 2006.

Further, we may license or acquire product candidates from others which would require additional cash outlays.

Contractual Commitments

Lease Payments

Future minimum lease payments under non-cancelable operating leases are as follows:

| Year ending December 31, | |
|--------------------------|--------------------|
| 2007 | \$1,233,000 |
| 2008 | 1,252,000 |
| 2009 | 1,259,000 |
| 2010 | 1,220,000 |
| 2011 | 1,219,000 |
| 2012 and beyond | 1,932,000 |
| | <u>\$8,115,000</u> |

Glaxo Collaboration Agreement

Under the terms of the Glaxo agreement, we reimburse Glaxo for a portion of certain third party expenses incurred by them relating to *Entereg*, pursuant to an agreed upon development plan and budget which is subject to annual review. We also incur certain third party expenses ourselves relating to *Entereg*, pursuant to an agreed upon development plan and budget, a portion of which are reimbursable to us by Glaxo. We record these expenses as incurred.

Other Service Agreements

We have entered into various agreements for services with third party vendors, including agreements to conduct clinical trials, to manufacture product candidates, and for consulting and other contracted services. We accrue the costs of these agreements based on estimates of work completed to date. We estimate that approximately \$14.4 million will be payable in future periods under arrangements in place at December 31, 2006. Of this amount, approximately \$4.0 million has been accrued for work estimated to have been completed as of December 31, 2006 and approximately \$10.4 million relates to future performance under these arrangements.

License and Research Agreements

With regard to our lead product, *Entereg*, we have commitments to Roberts and Eli Lilly. In November 1996, Roberts licensed from Eli Lilly certain intellectual property rights relating to *Entereg*. In June 1998, we entered into an option and license agreement with Roberts under which we licensed from Roberts the rights Roberts had licensed from Eli Lilly for *Entereg*. We have made license and milestone payments under this agreement totaling \$1.6 million. If *Entereg* receives regulatory approval, we are obligated to make an additional milestone payment of \$900,000 under this agreement, as well as royalties on commercial sales of *Entereg*. Our license to *Entereg* expires on the later of either the life of the last to expire of the licensed Eli Lilly patents or fifteen years from November 5, 1996, following which we will have a fully paid up license.

In August 2002, we entered into a separate license agreement with Eli Lilly under which we obtained an exclusive license to six issued U.S. patents and related foreign equivalents and know-how relating to peripherally selective opioid antagonists. We paid Eli Lilly \$4.0 million upon signing the agreement and are subject to additional clinical and regulatory milestone payments and royalty payments to Eli Lilly on sales, if any, of new products utilizing the licensed technology. Under this license agreement, we also agreed to pay Eli Lilly \$4.0 million upon acceptance for review of our NDA by the FDA, which payment was made in the third quarter of 2004.

In July 2003, we entered into a license agreement with EpiCept Corporation under which we licensed : exclusive rights to develop and commercialize in North America a sterile lidocaine patch which we were developing for management of postoperative incisional pain. We made a \$2.5 million payment to EpiCept upon execution of the agreement and a \$0.5 million payment to EpiCept in September 2005. We discontinued development of the sterile lidocaine patch and terminated the EpiCept license in the fourth quarter of 2006.

Net Cash Provided By Investing Activities and Investing Requirements Outlook

Net cash provided by investing activities for the year ended December 31, 2006 and 2005 relates primarily to the maturities of investment securities. Capital expenditures in 2006 and 2005 were primarily for purchase of laboratory equipment, furniture and fixtures and office equipment and leasehold improvements associated with our leased facility.

We expect to continue to fund operations through the maturities of investments in our portfolio. We expect to continue to require investments in information technology, laboratory and office equipment to support our research and development activities, and potential commercialization activities.

Net Cash Provided by Financing Activities and Financing Requirements Outlook

Net cash inflows provided by financing activities for the year ended December 31, 2006 resulted primarily from the sale of 5,750,000 shares of common stock at \$25.00 per share in February 2006. We received net proceeds from the offering of approximately \$135.1 million. In addition, we received \$12.4 million from the exercise of stock options in 2006.

We may never receive regulatory approval for any of our product candidates, generate product sales revenues, achieve profitable operations or generate positive cash flows from operations, and even if profitable operations are achieved, these may not be sustained on a continuing basis. We have invested a significant portion of our time and financial resources since our inception in the development of *Entereg*, and our potential to achieve revenues from product sales in the foreseeable future is dependent largely upon obtaining regulatory approval for and successfully commercializing *Entereg*, especially in the United States. Although we received an approvable letter from the FDA for *Entereg* in July 2005 and November 2006, there is no assurance that the FDA will approve *Entereg* in the future. We expect to continue to use our cash and investments resources to fund operating and investing activities. We believe that our existing cash, cash equivalents and short-term investments of approximately \$185.6 million as of December 31, 2006 will be sufficient to fund operations into 2009.

Results of Operations

This section should be read in conjunction with the discussion above under "Liquidity and Capital Resources".

Contract Revenues. Contract revenues were approximately \$15.1 million and \$15.7 million in 2006 and 2005, respectively. The decrease was primarily the result of a reduction in co-promotion revenues of \$1.8 million relating to the Arixtra co-promotion with Glaxo. This decrease was partially offset by an increase in revenues of \$1.2 million resulting from increased expenses incurred by us relating to *Entereg* and reimbursable by Glaxo under the collaboration agreement.

Contract revenues decreased in 2005 as compared to 2004 primarily due to the recognition in 2004 of \$10.0 million in milestone revenue received from Glaxo. Additionally, cost reimbursement revenues decreased as a result of a decrease in expenses incurred by us which are reimbursable by Glaxo under our collaboration agreement. These decreases were partially offset by a revenue increase in 2005 as compared to 2004 of \$4.2 million under our co-promotion arrangement with Glaxo relating to Arixtra®.

Research and Development Expenses. Our research and development expenses consist primarily of salaries and other personnel-related expense, costs of clinical trials, costs to manufacture product candidates, technology licensing costs, laboratory supply costs and facility-related costs. Research and development expenses increased to approximately \$56.7 million for the year ended December 31, 2006 from approximately \$49.6 million for the year ended December 31, 2005. Expenses increased principally due to a greater compensation expense of \$2.8 million relating to the adoption of FAS 123R and increased expenses associated with our combination product development program and sterile lidocaine patch program.

Research and development expenses increased to approximately \$49.6 million for the year ended December 31, 2005 from approximately \$48.8 million for the year ended December 31, 2004. This increase was due to increased expense for reimbursements owed Glaxo relating to the OBD program, an increase in expenses related to Study 314, increased expenses associated with other development programs and increased personnel costs. These increases were partially offset by the recognition of \$4.5 million in license fee expense related to *Entereg* in 2004.

Our research and development expenses can be identified as internal or external expenses. Internal expenses include expenses such as personnel, laboratory, and overhead related expenses. These expenses totaled \$25.1 million, \$21.8 million and \$21.1 million in the years ended December 31, 2006, 2005, and 2004, respectively, and are largely related to our *Entereg* development efforts. External expenses include expenses incurred with clinical research organizations, contract manufacturers, and other third party vendors and can be allocated to significant research and development programs as follows:

| | Years Ended December 31, | | |
|------------------------------|--------------------------|---------------------|---------------------|
| | 2006 | 2005 | 2004 |
| <i>Entereg</i> Program | \$19,563,818 | \$20,926,219 | \$24,893,900 |
| Combination Program | 4,406,978 | — | — |
| Sterile Patch Program | 2,923,765 | 2,025,581 | 1,839,580 |
| Delta Program | 2,493,115 | 2,797,485 | — |
| Other Programs | 2,203,730 | 2,053,492 | 1,001,391 |
| Total | <u>\$31,591,406</u> | <u>\$27,802,777</u> | <u>\$27,734,871</u> |

There are significant risks and uncertainties inherent in the preclinical and clinical studies associated with each of our research and development programs. These studies may yield varying results that could delay, limit or prevent a program's advancement through the various stages of product development, and significantly impact the costs to be incurred, and time involved, in bringing a program to completion. As a result, the cost to complete such programs, as well as the period in which net cash inflows from significant programs are expected to commence, are not reasonably estimable.

Marketing, General and Administrative Expenses. Our marketing, general and administrative expenses for the years ended December 31, 2006, 2005 and 2004 were approximately \$37.7 million, \$26.3 million and \$22.9 million, respectively.

The expense increase in 2006 was principally related to increased personnel expenses, including expenses associated with the implementation of FAS 123R of \$5.8 million, combined with additional marketing and sales expenses. The increase in 2005 is principally related to increased personnel expenses, including expenses associated with our sales force and the \$2.5 million restructuring charge associated with disbanding the sales force of approximately 35 people. The increase was partially offset by decreased legal fees.

Interest Income. Our interest income increased to \$9.0 million for the year ended December 31, 2006 from approximately \$3.4 million in the year ended December 31, 2005. This was primarily due to an increase in short-term investments resulting from the proceeds from the sale of common stock in February 2006 in addition to higher interest rates.

Other income (expense). Our other income increased to approximately \$0.5 million for the year ended December 31, 2006 and represents cash received from the sale of certain Pennsylvania research and development tax credits.

Net Loss Outlook

We have not generated any product sales revenues, have incurred operating losses since inception and have not achieved profitable operations. Our deficit accumulated during the development stage through December 31, 2006 aggregated approximately \$376.5 million, and we expect to continue to incur substantial losses in future periods.

We expect to continue to use cash resources to fund operating losses. We expect to continue to incur operating losses in 2007 and beyond due to continuing research and development expenses relating to *Entereg* and increased spending relating to other product development programs, including the combination product

program and the delta programs. We also expect to incur marketing costs in preparation for the potential commercialization of *Entereg*, however, sales related costs in future periods will be reduced due to the reduction in force instituted in December 2006.

We are highly dependent on the success of our research, development and licensing efforts and, ultimately, upon regulatory approval and market acceptance of our products under development, particularly our lead product candidate, *Entereg*. We may never receive regulatory approval for any of our product candidates, generate product sales revenues, achieve profitable operations or generate positive cash flows from operations, and even if profitable operations are achieved, these may not be sustained on a continuing basis.

Income Taxes

As of December 31, 2006, we had approximately \$271.1 million of Federal and \$268.0 million of state net operating loss carryforwards potentially available to offset future taxable income. The Federal and state net operating loss carryforwards will begin expiring in 2009 and 2006, respectively, if not utilized. In addition, the utilization of the state net operating loss carryforwards is subject to annual limitation. At December 31, 2006, we also had approximately \$8.4 million of Federal and \$737,000 of state research and development tax credit carryforwards, which begin expiring in 2011, and are available to reduce Federal and state income taxes.

The Tax Reform Act of 1986 (the "Act") provides for a limitation on the annual use of net operating loss and research and development tax credit carryforwards (following certain ownership changes, as defined by the Act) that could significantly limit our ability to utilize these carryforwards. We may have experienced various ownership changes, as defined by the Act, as a result of past financings. Additionally, because United States and certain state tax laws limit the time during which these carryforwards may be applied against future taxes, we may not be able to take full advantage of these attributes for Federal and state income tax purposes.

Recently Issued Accounting Pronouncements

In February 2006, the FASB issued FASB Staff Position No. FAS 123(R)-4, *Classification of Options and Similar Instruments Issued as Employee Compensation That Allow for Cash Settlement upon the Occurrence of a Contingent Event*. This position amends SFAS 123R to incorporate that a cash settlement feature that can be exercised only upon the occurrence of a contingent event that is outside the employee's control does not meet certain conditions in SFAS 123R until it becomes probable that the event will occur. The guidance in this FASB Staff Position shall be applied upon the initial adoption of Statement 123R. The Company adopted SFAS 123R in the first quarter of fiscal 2006.

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ("FIN 48"), an interpretation of FASB Statement No. 109, *Accounting for Income Taxes* ("SFAS 109"). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109. FIN 48 prescribes a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon examination. If the tax position is deemed "more-likely-than-not" to be sustained, the tax position is then measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured at the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. FIN 48 is required to be adopted by the Company in fiscal 2007. The adoption of FIN 48 will not have a material impact on our results of operations and financial position.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"). SFAS 157 clarifies the definition of fair value, establishes a framework for measuring fair value and expands disclosures on fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We do not expect the adoption of SFAS 157 to have a material impact on our consolidated results of operations and financial position.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Current Year Misstatements* ("SAB 108"). SAB 108 requires analysis of misstatements using both an income statement (rollover) approach and a balance sheet (iron curtain) approach in assessing materiality and provides for a one-time cumulative effect transition adjustment. SAB 108 is effective for annual financial statements issued for fiscal years ending after November 15, 2006. The adoption of SAB 108 did not have a material impact on our consolidated results of operations and financial position.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

A substantial portion of our assets are investment grade fixed income securities, principally U.S. Treasury obligations. The market value of such investments fluctuates with current market interest rates. In general, as rates increase, the market value of a debt instrument would be expected to decrease. The opposite is also true. To minimize such market risk, we have in the past and, to the extent possible, will continue in the future, to hold such debt instruments to maturity at which time the debt instrument will be redeemed at its stated or face value. Due to the short duration and nature of these instruments, we do not believe that we have a material exposure to interest rate risk related to our investment portfolio. The investment portfolio at December 31, 2006 totaled \$182.3 million, and the weighted-average interest rate was approximately 5.09% with maturities of investments ranging up to 12 months.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. A list of the financial statements filed herewith can be found at "Item 15. Exhibits and Financial Statement Schedules".

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

For the year ended December 31, 2006, we carried out an evaluation, under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Vice President and Chief Financial Officer (the principal finance and accounting officer), of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rules 13a-15(b) and 15d-15(b) under the Exchange Act, as of the end of the period covered by this report. Based upon this evaluation, our President and Chief Executive Officer and our Vice President and Chief Financial Officer concluded that, as of December 31, 2006, our disclosure controls and procedures have been designed and are being operated in a manner that provides reasonable assurance that the information required to be disclosed by Adolor (the Company) in reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Commission. A control system, no matter how well designed and operated, cannot provide assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

The management of Adolor Corporation is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a - 15(f) or 15d - 15(f) promulgated under the Securities Exchange Act of 1934, as amended. Adolor's internal control system was designed to provide reasonable assurance to the company's management and board of directors regarding the preparation and fair presentation of published financial statements. There have not been any changes in our internal control over financial reporting during the quarter ended December 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Adolor's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2006. In making this assessment, it used the criteria set forth by the Committee on

Sponsoring Organizations of the Treadway Commission ("COSO") in *Internal Control-Integrated Framework*. Based on our assessment we believe that, as of December 31, 2006, the Company's internal control over financial reporting is effective based on those criteria.

Adolor's independent registered public accounting firm has issued an audit report on our assessment of the Company's internal control over financial reporting. This report appears below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Adolor Corporation:

We have audited management's assessment, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A, that Adolor Corporation (the "Company") maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control—Integrated Framework* issued by *The Committee of Sponsoring Organizations of the Treadway Commission* (COSO). Adolor Corporation management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Adolor Corporation maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on criteria established in *Internal Control—Integrated Framework* issued by COSO. Also, in our opinion, Adolor Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on the criteria established in *Internal Control—Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Adolor Corporation and subsidiary as of December 31, 2006 and 2005, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2006, and for the period from August 9, 1993 (inception) to December 31, 2006, and our report dated February 26, 2007 expressed an unqualified opinion on those consolidated financial statements:

/s/ KPMG LLP

Philadelphia, Pennsylvania
February 26, 2007

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

We incorporate by reference the information contained under the captions "Election of Directors, Item 1 on Proxy Card", "Executive Officers of the Registrant", and "Section 16(a) Beneficial Ownership Reporting Compliance" in our Definitive Proxy Statement related to our annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Annual Report pursuant to Section 14(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

ITEM 11. EXECUTIVE COMPENSATION

We incorporate by reference the information contained under the caption "Executive Compensation" in our Definitive Proxy Statement related to our annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Annual Report pursuant to Section 14(a) of the Exchange Act.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

We incorporate by reference the information contained under the captions "Security Ownership of Certain Beneficial Owners and Directors and Officers" in our Definitive Proxy Statement related to our annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Annual Report pursuant to Section 14(a) of the Exchange Act and found earlier in this Form 10-K in Part II, Item 5(d) under the caption "Securities Authorized for Issuance under Equity Compensation Plans".

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

We incorporate by reference the information contained under the caption "Certain Relationships and Related Transactions" in our Definitive Proxy Statement related to our annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Annual Report pursuant to Section 14(a) of the Exchange Act.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

We incorporate by reference the information contained under the caption "Ratification of Appointment of Independent Registered Public Accounting Firm Audit Committee Report—Audit Fees; Audit-Related Fees; Tax Fees; All Other Fees" in our Definitive Proxy Statement related to our annual meeting of stockholders, to be filed within 120 days after the end of the year covered by this Annual Report pursuant to Section 14(a) of the Exchange Act.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) 1. Financial Statements

Reference is made to the Index to Consolidated Financial Statements on page F-1 of this Annual Report.

2. Financial Statement Schedules

None

(b) Exhibits

Reference is made to the Exhibit Index on page 55 of this Annual Report for a list of exhibits required by Item 601 of Regulation S-K to be filed as part of this Annual Report.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Security Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: February 27, 2007

ADOLOR CORPORATION

By: /s/ MICHAEL R. DOUGHERTY

Name: Michael R. Dougherty

Title: *President, Chief Executive Officer and Director*

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|--|-------------------|
| <u>/s/ MICHAEL R. DOUGHERTY</u> Michael R. Dougherty | President, Chief Executive Officer and Director (Principal Executive Officer) | February 27, 2007 |
| <u>/s/ THOMAS P. HESS</u> Thomas P. Hess | Vice President, Chief Financial Officer (Principal Financial and Accounting Officer) | February 27, 2007 |
| <u>/s/ ARMANDO ANIDO</u> Armando Anido | Director | February 27, 2007 |
| <u>/s/ PAUL GODDARD</u> Paul Goddard | Director | February 27, 2007 |
| <u>/s/ GEORGE V. HAGER, JR.</u> George V. Hager, Jr. | Director | February 27, 2007 |
| <u>/s/ DAVID M. MADDEN</u> David M. Madden | Director | February 27, 2007 |
| <u>/s/ CLAUDE H. NASH</u> Claude H. Nash | Director | February 27, 2007 |
| <u>/s/ ROBERT T. NELSEN</u> Robert T. Nelsen | Director | February 27, 2007 |
| <u>/s/ DONALD E. NICKELSON</u> Donald E. Nickelson | Director | February 27, 2007 |

EXHIBIT INDEX

| Exhibit Number | Description |
|-------------------|--|
| 3.1 | Amended and Restated Certificate of Incorporation of Adolor (incorporated by reference to Exhibit 3.1 to the Report on Form 10-Q filed by the Company on May 17, 2001). |
| 3.2 | Restated Bylaws of the Company as amended February 26, 2004 (incorporated by reference to Exhibit 3.2 to Report on Form 10-K filed by the Company on March 4, 2004). |
| 4.1 | Rights Agreement, dated as of February 20, 2001, between Adolor and StockTrans, Inc., as Rights Agent (incorporated by reference to Exhibit 4.1 to Form 8-K filed by the Company on February 23, 2001), which included as Exhibit B thereto the Form of Rights Certificate, incorporated by reference to Exhibit 1.1 to the Company's Registration Statement on Form 8-A, dated February 22, 2001. |
| 4.2 | Form of Common Stock Certificate (incorporated by reference to Exhibit 4.14 to Amendment No. 3 to the Registration Statement filed by the Company on March 21, 2000). |
| 10.1 | Amended and Restated 1994 Equity Compensation Plan. ¹⁴ |
| 10.2 | Adolor Corporation 2003 Stock-Based Incentive Compensation Plan (incorporated by reference to Appendix B to the Proxy Statement filed by the Company on March 29, 2006). ⁴ |
| 10.3 | Third Amendment to the Adolor Corporation 2003 Stock-Based Incentive Compensation Plan (incorporated by reference to Exhibit 10.2 to Form 8-K filed by the Company on December 19, 2006). ⁴ |
| 10.4 | Option and License Agreement between Adolor and Roberts Laboratories, Inc., dated June 10, 1998 (incorporated by reference to Exhibit 10.2 to Amendment No. 1 to the Registration Statement filed by the Company on February 18, 2000). ² |
| 10.5 | Amended and Restated Build to Suit Lease between the Company and 700 Pennsylvania Drive Associates, dated February 27, 2003 (incorporated by reference to Exhibit 10.4 to Form 10-K filed by the Company on March 18, 2003). |
| 10.6 | License Agreement between Adolor Corporation and Eli Lilly and Company, dated August 8, 2002 (incorporated by reference to Exhibit 10.1 to Form 10-Q filed by the Company on November 1, 2002). ² |
| 10.7 | Collaboration Agreement dated as of April 14, 2002, by and between the Company and Glaxo Group Limited (incorporated by reference to Exhibit 10.1 to Form 8-K/A filed by the Company on December 22, 2005). ² |
| 10.8 | Amendment No. 1, dated as of June 22, 2004, to the Collaboration Agreement with Glaxo Group Limited (incorporated by reference to Exhibit 10.1 to Form 10-Q filed by the Company on August 4, 2004). |
| 10.9 | Amendment No. 2, dated December 22, 2004, to Collaboration Agreement between Glaxo Group Limited and the Company (incorporated by reference to Exhibit 10.1 to Form 8-K/A filed by the Company on February 25, 2005). ² |
| 10.10 | Distribution Services Agreement between SmithKline Beecham Corporation and the Company, dated June 29, 2004 (incorporated by reference to Exhibit 10.2 to Form 10-Q filed by the Company on August 4, 2004). ² |
| 10.11 | API Compound Supply Agreement Between the Company and Torcan Chemical Ltd., dated July 13, 2004 (incorporated by reference to Exhibit 10.3 to Form 10-Q filed by the Company on August 4, 2004). ² |

| <u>Exhibit Number</u> | <u>Description</u> |
|---------------------------|--|
| 10.12 | API Compound Supply Agreement Between the Company and Girindus AG, dated July 6, 2004 (incorporated by reference to Exhibit 10.4 to Form 10-Q filed by the Company on August 4, 2004). ² |
| 10.13 | Drug Product Supply Agreement between the Company and Pharmaceuticals International, Inc., dated July 1, 2004 (incorporated by reference to Exhibit 10.5 to Form 10-Q filed by the Company on August 4, 2004). ² |
| 10.14 | ROW Supply Agreement dated September 13, 2004 between Glaxo Group Limited and the Company (incorporated by reference to Exhibit 10.1 to Form 8-K filed by the Company on September 15, 2004). ² |
| 10.15 | Adolor Corporation Executive Severance Pay Program (incorporated by reference to Exhibit 10.2 to Form 10-Q filed by the Company on November 1, 2002). ⁴ |
| 10.16 | Letter Agreement between the Company and Martha E. Manning, dated June 30, 2002 (incorporated by reference to Exhibit 10.2 to Form 10-Q filed by the Company on August 13, 2002). ⁴ |
| 10.17 | Letter Agreement between the Company and Michael R. Dougherty, dated October 24, 2002 (incorporated by reference to Exhibit 10.15 to Form 10-K filed by the Company on March 18, 2003). ⁴ |
| 10.18 | Amendment dated January 26, 2004 to Letter Agreement between the Company and Michael R. Dougherty, dated October 24, 2002 (incorporated by reference to Exhibit 10.6 to Form 10-K filed by the Company on March 4, 2004). ⁴ |
| 10.19 | Letter Agreement between the Company and Michael R. Dougherty dated December 14, 2006 (incorporated by reference to Exhibit 10.1 to Form 8-K filed by the Company on December 14, 2006). ⁴ |
| 10.20 | Stock Award Letter Agreement between the Company and Michael R. Dougherty dated December 14, 2006 (incorporated by reference to Exhibit 10.2 to Form 8-K filed by the Company on December 14, 2006). ⁴ |
| 10.21 | Letter Agreement between the Company and David Jackson, dated January 7, 2007 (incorporated by reference to Exhibit 10.1 to Form 8-K filed by the Company on January 9, 2007). ⁴ |
| 10.22 | Letter Agreement between the Company and James E. Barrett, Ph.D., dated June 23, 2004 (incorporated by reference to Exhibit 10.6 to Form 10-Q filed by the Company on August 4, 2004). ⁴ |
| 10.23 | Letter Agreement between the Company and James Barrett dated October 7, 2005 (incorporated by reference to Exhibit 10.1 to Form 8-K filed by the Company on October 7, 2005). ⁴ |
| 10.24 | Letter Agreement between the Company and Thomas Hess dated September 16, 2005 (incorporated by reference to Exhibit 10.1 to Form 8-K filed by the Company on October 31, 2005). ⁴ |
| 10.25 | Letter Agreement between the Company and David Madden dated August 1, 2005 (incorporated by reference to Exhibit 10.1 to Form 8-K filed by the Company on August 2, 2005). ⁴ |
| 10.26 | Letter Agreement between the Company and David M. Madden dated August 8, 2006 (incorporated by reference to Exhibit 10.1 to Form 8-K filed by the Company on August 9, 2006). ⁴ |
| 10.27 | Letter Agreement between the Company and Roger D. Graham, Jr. dated as of April 14, 2005 (incorporated by reference to Exhibit 10.1 to Form 8-K filed by the Company on April 19, 2005). ⁴ |
| 10.28 | Form of Stock Option Agreement (incorporated by reference to Exhibit 10.26 to Form 10-K filed by the Company on March 1, 2005). ⁴ |

| <u>Exhibit Number</u> | <u>Description</u> |
|---------------------------|---|
| 10.29 | Form of Stock Option Agreement for members of the Board of Directors of Adolor Corporation (incorporated by reference to Exhibit 10.1 to Form 10-Q filed by the Company on July 31, 2006). ⁴ |
| 10.30 | Form of Deferred Stock Award. ^{1 4} |
| 10.31 | Incentive Compensation Plan. ^{1 4} |
| 23.1 | Consent of KPMG LLP. ¹ |
| 31.1 | Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. ¹ |
| 31.2 | Certification pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. ¹ |
| 32.1 | Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002. ¹ |
| 32.2 | Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002. ¹ |

¹ Filed herewith.

² Confidential treatment granted.

³ Confidential treatment has been requested with respect to portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

⁴ Compensation plan or arrangement in which directors and executive officers are eligible to participate.

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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

The following Consolidated Financial Statements, and the related Notes thereto, of Adolor Corporation and subsidiary and the Report of Independent Registered Public Accounting Firm are filed as a part of this Annual Report on Form 10-K.

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| Report of Independent Registered Public Accounting Firm | F-2 |
| Financial Statements: | |
| Consolidated Balance Sheets at December 31, 2006 and 2005 | F-3 |
| Consolidated Statements of Operations for the years ended December 31, 2006, 2005 and 2004, and for the period from August 9, 1993 (inception) to December 31, 2006 | F-4 |
| Consolidated Statements of Comprehensive Loss for the years ended December 31, 2006, 2005 and 2004, and for the period from August 9, 1993 (inception) to December 31, 2006 | F-5 |
| Consolidated Statements of Stockholders' Equity for the period from August 9, 1993 (inception) to December 31, 2003, and for the years ended December 31, 2004, 2005 and 2006 | F-6 |
| Consolidated Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004, and for the period from August 9, 1993 (inception) to December 31, 2006 | F-8 |
| Notes to Consolidated Financial Statements | F-9 |

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Adolor Corporation:

We have audited the accompanying consolidated balance sheets of Adolor Corporation (a development-stage company) and subsidiary as of December 31, 2006 and 2005, and the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2006, and for the period from August 9, 1993 (inception) to December 31, 2006. These consolidated financial statements are the responsibility of the management of Adolor Corporation. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Notes 2 and 7 to the consolidated financial statements, effective January 1, 2006, the Company adopted the fair value method of accounting for stock-based compensation as required by Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Adolor Corporation (a development-stage company) and subsidiary as of December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2006, and for the period from August 9, 1993 (inception) to December 31, 2006, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the internal control over financial reporting of Adolor Corporation and subsidiary as of December 31, 2006, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee on Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 26, 2007, expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania
February 26, 2007

ADOLOR CORPORATION AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS

| | December 31, 2006 | December 31, 2005 |
|---|-----------------------|-----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 3,278,858 | \$ 1,729,099 |
| Short-term investments | 182,283,151 | 101,346,020 |
| Accounts receivable from agreements | 3,279,374 | 3,214,834 |
| Prepaid expenses and other current assets | 4,490,950 | 2,452,191 |
| Total current assets | 193,332,333 | 108,742,144 |
| Equipment and leasehold improvements, net | 7,022,494 | 8,197,470 |
| Other assets | 242,753 | 297,003 |
| Total assets | <u>\$ 200,597,580</u> | <u>\$ 117,236,617</u> |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,662,701 | \$ 3,353,296 |
| Accrued expenses | 13,210,311 | 11,395,407 |
| Deferred licensing fees and rent—current | 4,329,192 | 4,329,192 |
| Total current liabilities | 20,202,204 | 19,077,895 |
| Deferred licensing fees and rent—non-current | 27,136,268 | 31,465,432 |
| Other liabilities | 78,480 | — |
| Total liabilities | 47,416,952 | 50,543,327 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Series A Junior Participating preferred stock, \$0.01 par value; 35,000 shares authorized; none issued and outstanding | — | — |
| Preferred stock, \$0.01 par value; 1,000,000 shares authorized; none issued and outstanding | — | — |
| Common stock, par value \$0.0001 per share; 99,000,000 shares authorized; 45,999,543 and 39,106,362 shares issued and outstanding at December 31, 2006 and 2005, respectively | 4,592 | 3,911 |
| Additional paid-in capital | 529,682,107 | 373,751,232 |
| Deferred compensation | — | (1,263) |
| Unrealized losses on available for sale securities | (4,563) | (297,460) |
| Deficit accumulated during the development stage | (376,501,508) | (306,763,130) |
| Total stockholders' equity | 153,180,628 | 66,693,290 |
| Total liabilities and stockholders' equity | <u>\$ 200,597,580</u> | <u>\$ 117,236,617</u> |

The accompanying notes are an integral part of the consolidated financial statements.

ADOLOR CORPORATION AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS

Years ended December 31, 2006, 2005 and 2004, and for the period from
August 9, 1993 (inception) to December 31, 2006

| | Year ended December 31, | | | Period from August 9, 1993 (inception) to December 31, 2006 |
|--|-------------------------|-----------------------|-----------------------|---|
| | 2006 | 2005 | 2004 | |
| Contract revenues | \$ 15,087,411 | \$ 15,718,876 | \$ 25,541,627 | \$ 107,075,579 |
| Operating expenses incurred during the development stage: | | | | |
| Research and development | 56,659,750 | 49,630,590 | 48,765,515 | 359,382,217 |
| Marketing, general and administrative | 37,689,565 | 26,292,904 | 22,870,535 | 157,657,431 |
| Total operating expenses | 94,349,315 | 75,923,494 | 71,636,050 | 517,039,648 |
| Other income: | | | | |
| Interest income | 8,991,261 | 3,401,345 | 2,509,519 | 33,279,550 |
| Other income (expense) | 532,265 | 6,643 | (1,580) | 183,011 |
| Total other income | 9,523,526 | 3,407,988 | 2,507,939 | 33,462,561 |
| Net loss | (69,738,378) | (56,796,630) | (43,586,484) | (376,501,508) |
| Undeclared dividends attributable to mandatorily redeemable convertible preferred stock | — | — | — | 10,546,314 |
| Beneficial conversion feature on mandatorily redeemable convertible preferred stock | — | — | — | 48,905,779 |
| Net loss allocable to common stockholders | <u>\$(69,738,378)</u> | <u>\$(56,796,630)</u> | <u>\$(43,586,484)</u> | <u>\$(435,953,601)</u> |
| Basic and diluted net loss per share allocable to common stockholders | <u>\$ (1.56)</u> | <u>\$ (1.45)</u> | <u>\$ (1.12)</u> | |
| Shares used in computing basic and diluted net loss per share allocable to common stockholders | <u>44,731,350</u> | <u>39,088,126</u> | <u>38,923,681</u> | |

The accompanying notes are an integral part of the consolidated financial statements.

ADOLOR CORPORATION AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

**Years ended December 31, 2006, 2005, and 2004,
and the period August 9, 1993 (inception) to December 31, 2006**

| | Years ended December 31, | | | Period from August 9, 1993 (inception) to December 31, 2006 |
|---|--------------------------|-----------------------|-----------------------|---|
| | 2006 | 2005 | 2004 | |
| Net loss | <u>\$(69,738,378)</u> | <u>\$(56,796,630)</u> | <u>\$(43,586,484)</u> | <u>\$(376,501,508)</u> |
| Other comprehensive income (loss): | | | | |
| Unrealized gains (losses) on available for sale securities | 292,897 | 165,997 | (684,681) | (4,563) |
| Realized loss on available for sale securities | <u>—</u> | <u>7,385</u> | <u>114,086</u> | <u>30,957</u> |
| Comprehensive loss | <u>\$(69,445,481)</u> | <u>\$(56,623,248)</u> | <u>\$(44,157,079)</u> | <u>\$(376,475,114)</u> |

The accompanying notes are an integral part of the consolidated financial statements.

ADOLOR CORPORATION AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

For the period from August 9, 1993 (inception) to December 31, 2003, for the years ended
December 31, 2004, 2005, and 2006

| | Common stock | | Additional paid-in capital | Deferred compensation | Unrealized gain (loss) on available for sale securities | Deficit accumulated during the development stage | Total stockholders' equity |
|--|---------------------|----------------|----------------------------------|--------------------------|--|--|----------------------------------|
| | Number of shares | Amount | | | | | |
| Inception, August 9, 1993 | — | \$ — | \$ — | \$ — | \$ — | \$ — | \$ — |
| Issuance of common stock to founder in November 1994 at \$.001 per share | 100,000 | 10 | 12,490 | (12,400) | — | — | 100 |
| Issuance of restricted stock in November 1994 and May 1996 | 565,411 | 57 | 72,355 | (66,767) | — | — | 5,645 |
| Issuance of common stock for technology license agreements in December 1995 at \$.125 per share | 50,000 | 5 | 6,245 | — | — | — | 6,250 |
| Issuance of common stock for technology license agreements | 3,829 | — | 50,006 | — | — | — | 50,006 |
| Issuance of common stock for services in April 1999 at \$3.736 per share | 3,570 | — | 13,339 | — | — | — | 13,339 |
| Value attributed to issuance of warrants | — | — | 60,000 | — | — | — | 60,000 |
| Notes issued to employees for stock options exercised | — | — | (1,056,488) | — | — | — | (1,056,488) |
| Payments on notes granted to employees for stock options | — | — | 971,197 | — | — | — | 971,197 |
| Interest receivable converted to principal on employee notes | — | — | (128,924) | — | — | — | (128,924) |
| Accretion of Series H preferred stock issuance costs | — | — | (281,794) | — | — | — | (281,794) |
| Forfeiture of stock options | (71,247) | (7) | (1,706,296) | 1,706,303 | — | — | — |
| Exercise of stock options | 2,506,529 | 251 | 3,687,580 | — | — | — | 3,687,831 |
| Unrealized gain on investments | — | — | — | — | 221,224 | — | 221,224 |
| Conversion of preferred shares | 18,818,421 | 1,882 | 80,381,821 | — | — | — | 80,383,703 |
| Net proceeds from initial public offering | 6,900,000 | 690 | 95,375,779 | — | — | — | 95,376,469 |
| Reduction of estimated offering costs | — | — | 400,000 | — | — | — | 400,000 |
| Net proceeds from issuance of newly registered shares of common stock | 9,900,000 | 990 | 170,546,726 | — | — | — | 170,547,716 |
| Issuance of common stock for bonus awards and under an employment agreement | 16,609 | 1 | 223,770 | (2,172) | — | — | 221,599 |
| Deferred compensation resulting from grant of stock options | — | — | 23,911,011 | (23,911,011) | — | — | — |
| Accelerated amortization and cancellation of deferred compensation resulting from the acceleration of vesting of stock options | — | — | (347,382) | 3,451,714 | — | — | 3,104,332 |
| Amortization of deferred compensation | — | — | — | 18,076,745 | — | — | 18,076,745 |
| Net loss | — | — | — | — | — | (206,380,016) | (206,380,016) |
| Balance, December 31, 2003 | <u>38,793,122</u> | <u>\$3,879</u> | <u>\$372,191,435</u> | <u>\$ (757,588)</u> | <u>\$221,224</u> | <u>\$(206,380,016)</u> | <u>\$ 165,278,934</u> |

The accompanying notes are an integral part of the consolidated financial statements.

ADOLOR CORPORATION AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY—Continued

For the period from August 9, 1993 (inception) to December 31, 2003, for the years ended
December 31, 2004, 2005 and 2006

| | Common stock | | Additional paid-in capital | Deferred compensation | Unrealized gain (loss) on available for sale securities | Deficit accumulated during the development stage | Total stockholders' equity |
|--|---------------------|---------|----------------------------------|--------------------------|--|--|----------------------------------|
| | Number of shares | Amount | | | | | |
| Balance, December 31, 2003 | 38,793,122 | \$3,879 | \$372,191,435 | \$ (757,588) | \$ 221,224 | \$(206,380,016) | \$165,278,934 |
| Payments on notes granted to employees for stock options | — | — | 2,754 | — | — | — | 2,754 |
| Interest receivable converted to principal on employee notes | — | — | (2,935) | — | — | — | (2,935) |
| Exercise of stock options | 287,223 | 29 | 1,056,575 | — | — | — | 1,056,604 |
| Unrealized loss on investments | — | — | — | — | (684,681) | — | (684,681) |
| Deferred compensation resulting from grant of stock options adjustment | — | — | 357,602 | (357,602) | — | — | — |
| Amortization of deferred compensation | — | — | — | 1,095,725 | — | — | 1,095,725 |
| Net loss | — | — | — | — | — | (43,586,484) | (43,586,484) |
| Balance, December 31, 2004 | 39,080,345 | \$3,908 | \$373,605,431 | \$ (19,465) | \$(463,457) | \$(249,966,500) | \$123,159,917 |
| Payments on notes granted to employees for stock options | — | — | 15,742 | — | — | — | 15,742 |
| Interest receivable converted to principal on employee notes | — | — | (3,136) | — | — | — | (3,136) |
| Exercise of stock options | 26,017 | 3 | 133,195 | — | — | — | 133,198 |
| Unrealized gain on investments | — | — | — | — | 165,997 | — | 165,997 |
| Amortization of deferred compensation | — | — | — | 18,202 | — | — | 18,202 |
| Net loss | — | — | — | — | — | (56,796,630) | (56,796,630) |
| Balance, December 31, 2005 | 39,106,362 | \$3,911 | \$373,751,232 | \$ (1,263) | \$(297,460) | \$(306,763,130) | \$ 66,693,290 |
| Net proceeds from issuance of newly registered shares of common stock | 5,750,000 | 575 | 135,054,860 | — | — | — | 135,055,435 |
| Compensation expense under FAS123R | — | — | 8,671,724 | — | — | — | 8,671,724 |
| Reclassification of stock options issued to Consultants | — | — | (300,428) | — | — | — | (300,428) |
| Reclassification of stock options exercised by Consultants | — | — | 103,652 | — | — | — | 103,652 |
| Payments on notes granted to employees for stock options | — | — | 35,809 | — | — | — | 35,809 |
| Interest receivable converted to principal on employee notes | — | — | (766) | — | — | — | (766) |
| Exercise of stock options | 1,063,181 | 106 | 12,366,024 | — | — | — | 12,366,130 |
| Restricted Stock Issued | 80,000 | — | — | — | — | — | — |
| Unrealized gain on investments | — | — | — | — | 292,897 | — | 292,897 |
| Amortization of deferred compensation | — | — | — | 1,263 | — | — | 1,263 |
| Net Loss | — | — | — | — | — | (69,738,378) | (69,738,378) |
| Balance, December 31, 2006 | 45,999,543 | \$4,592 | \$529,682,107 | \$ — | \$ (4,563) | \$(376,501,508) | \$153,180,628 |

The accompanying notes are an integral part of the consolidated financial statements.

ADOLOR CORPORATION AND SUBSIDIARY
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years ended December 31, 2006, 2005 and 2004, and for the period from
August 9, 1993 (inception) to December 31, 2006

| | Year ended December 31, | | | Period from August 9, 1993 (inception) to December 31, 2006 |
|--|-------------------------|-----------------|-----------------|---|
| | 2006 | 2005 | 2004 | |
| Net cash flows from operating activities: | | | | |
| Net loss | \$ (69,738,378) | \$ (56,796,630) | \$ (43,586,484) | \$ (376,501,508) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Non-cash compensation expense | 8,554,691 | 18,202 | 1,095,725 | 31,071,295 |
| Non-cash warrant value | — | — | — | 60,000 |
| Depreciation expense | 2,594,786 | 2,690,082 | 2,384,616 | 12,883,937 |
| Non-cash benefit from the trade of equipment | — | — | — | 120,000 |
| (Gain)/loss on the sale of equipment | — | (22,471) | — | (42,698) |
| Issuance of common stock for technology license agreements | — | — | — | 56,256 |
| Changes in assets and liabilities: | | | | |
| Accounts receivable from agreements | (64,540) | 149,042 | (284,119) | (3,279,374) |
| Prepaid expenses and other current assets | (2,038,759) | 90,502 | 403,561 | (4,490,950) |
| Other assets | 54,250 | (197,003) | 69,915 | (242,753) |
| Accounts payable | (690,595) | 249,887 | 1,560,710 | 2,662,701 |
| Accrued expenses | 1,814,904 | (320,825) | (3,243,944) | 13,210,311 |
| Deferred licensing fees and rent | (4,329,164) | (4,329,203) | (4,166,676) | 31,465,460 |
| Net cash used in operating activities | (63,842,805) | (58,468,417) | (45,766,696) | (293,027,323) |
| Net cash flows from investing activities: | | | | |
| Purchases of equipment and leasehold improvements | (1,419,810) | (1,117,035) | (2,456,012) | (20,139,912) |
| Proceeds from the sale of equipment | — | 25,245 | — | 169,518 |
| Purchases of short-term investments | (342,644,234) | (73,230,372) | (204,047,348) | (1,193,926,344) |
| Maturities/sales of short-term investments | 262,000,000 | 127,438,457 | 252,809,848 | 1,011,638,630 |
| Net cash (used in) / provided by investing activities | (82,064,044) | 53,116,295 | 46,306,488 | (202,258,108) |
| Net cash flows from financing activities: | | | | |
| Net proceeds from issuance of mandatorily redeemable convertible preferred stock and Series B warrants | — | — | — | 78,501,909 |
| Proceeds from Series D mandatorily redeemable convertible preferred stock subscription | — | — | — | 600,000 |
| Net proceeds from issuance of restricted common stock and exercise of common stock options | 12,366,130 | 133,198 | 1,056,604 | 16,193,019 |
| Proceeds from notes payable—related parties | — | — | — | 1,000,000 |
| Proceeds from notes payable | — | — | — | 1,832,474 |
| Payment of notes payable | — | — | — | (1,832,474) |
| Proceeds received on notes receivable | 35,809 | 15,742 | 2,754 | 1,025,502 |
| Interest receivable converted to principal on notes | (766) | (3,136) | (2,935) | (135,761) |
| Net proceeds from issuance of common stock | 135,055,435 | — | — | 401,379,620 |
| Net cash provided by financing activities | 147,456,608 | 145,804 | 1,056,423 | 498,564,289 |
| Net increase / (decrease) in cash and cash equivalents | 1,549,759 | (5,206,318) | 1,596,215 | 3,278,858 |
| Cash and cash equivalents at beginning of period | 1,729,099 | 6,935,417 | 5,339,202 | — |
| Cash and cash equivalents at end of period | \$ 3,278,858 | \$ 1,729,099 | \$ 6,935,417 | \$ 3,278,858 |
| Supplemental disclosure of cash flow information: | | | | |
| Cash paid for interest | \$ — | \$ 15,828 | \$ 1,580 | \$ 240,438 |
| Supplemental disclosure of non-cash financing activities: | | | | |
| Unrealized gains (losses) on available for sale securities | \$ 292,897 | \$ 165,997 | \$ (684,681) | \$ (4,563) |
| Deferred compensation from issuance of common stock, restricted common stock and common stock options | — | — | 357,602 | 24,496,376 |
| Issuance of common stock for technology license agreements or for services | — | — | — | 19,589 |
| Conversion of Series A through H (excluding D) preferred stock for common stock | — | — | — | 80,383,703 |
| Conversion of stock subscription to Series D mandatorily redeemable preferred stock | — | — | — | 600,000 |
| Conversion of bridge financing, including accrued interest, to Series B mandatorily redeemable preferred stock | — | — | — | 1,019,787 |

The accompanying notes are an integral part of the consolidated financial statements.

ADOLOR CORPORATION AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION AND BUSINESS ACTIVITIES

Adolor ("the Company") is a development stage biopharmaceutical corporation that was formed in 1993. The Company specializes in the discovery, development and commercialization of prescription pain management products. The Company has a number of product candidates that are in various stages of development ranging from preclinical studies to advanced stage clinical trials. The Company's lead product candidate, Entereg® (alvimopan), is designed to selectively block the unwanted effects of opioid analgesics on the gastrointestinal ("GI") tract. The Company is collaborating with Glaxo Group Limited ("Glaxo") for the global development and commercialization of *Entereg* in multiple indications. The Company is also developing a product that combines alvimopan with an opioid analgesic. In addition, the Company is developing a Delta opioid agonist which is currently in phase I clinical safety and tolerability testing. The Company's other product candidates are in preclinical development for treating moderate-to-severe pain conditions.

Currently, the Company's revenues are derived from its collaboration and co-promotion agreements with Glaxo. The Company has not generated any product sales revenues, has incurred operating losses since inception, and has not achieved profitable operations. The Company's deficit accumulated during the development stage through December 31, 2006 aggregated approximately \$376.5 million, and the Company expects to continue to incur substantial losses in future periods. The Company is highly dependent on the success of the Company's research, development and licensing efforts and, ultimately, upon regulatory approval and market acceptance of its products under development, particularly its lead product candidate, *Entereg*.

2. BASIS OF ACCOUNTING AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The Consolidated Financial Statements include the accounts of the Company and its wholly owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation. The Company's wholly owned subsidiary was dissolved in June 2005.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term nature.

Short-term Investments

The Company's entire portfolio of short-term investments is currently classified as available for sale and is stated at fair value as determined by quoted market values. Investments are held in investment grade fixed income securities, principally United States Treasury obligations. All investments are considered short-term and are classified as current assets, including securities with maturities in excess of one year, as management has the option to sell them at any time. Changes in net unrealized gains and losses are included as a separate component of stockholders' equity and comprehensive loss. For purposes of determining realized gains and losses, the cost of short-term investments sold is based upon specific identification. The Company has not experienced any other-than-temporary losses.

Concentration of Credit Risk

The Company invests its excess cash in accordance with a policy objective that seeks both liquidity and safety of principal. The policy limits investments to instruments issued by the U.S. government and commercial

ADOLOR CORPORATION AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(continued)

institutions with strong investment grade credit ratings and places restrictions on maturity terms and concentrations by type and issuer.

Equipment and Leasehold Improvements

Purchases of equipment (consisting of computer, office and laboratory equipment), furniture and fixtures and leasehold improvements are recorded at cost. Depreciation and amortization is provided using the straight-line method over the estimated useful lives of the assets or lease term, whichever is shorter, generally three to seven years. Expenditures for repairs and maintenance are charged to expense as incurred.

Revenue Recognition

The Company records a liability for deferred revenue for amounts received as upfront payments under collaboration agreements in which the Company has continuing involvement. The Company recognizes such deferred amounts as revenue ratably over the estimated contract performance period. Such revenue recognition may be accelerated in the event of contract termination prior to completion of the expected performance period or lengthened if the development period exceeds the initial estimate. Based on the receipt in November 2006 of the second approvable letter from the FDA, management has revised the expected performance period and will extend the period by two years. Milestone amounts are recorded as revenue when the milestone event is achieved. Amounts reimbursable for costs incurred pursuant to the terms of collaboration and co-promotion agreements are recorded as revenue in the period in which the reimbursable cost is incurred. Such revenues are determined based on estimates of the reimbursable amount and are subject to verification by the collaborators.

Research and Development Expenses

Research and product development costs are charged to expense as incurred. Costs incurred under agreements with third parties are charged to expense as incurred in accordance with the specific contractual performance terms of such agreements. Research and development expenses include, among other costs, salaries and other personnel-related costs, costs to conduct clinical trials, costs to manufacture drug candidates and clinical supplies, laboratory supplies costs and facility related costs.

Legal Matters

The Company accrues for liabilities related to litigation matters when the information available indicates that it is probable that a liability exists and can be reasonably estimated. Legal costs such as outside counsel fees and expenses are charged to expense in the period incurred.

Accounting for Income Taxes

Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all of the tax benefits will not be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

Segment Information

The Company is managed and operated as one business. The Company is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of business or separate business entities with respect to any of its product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate product areas, or by location, and does not have separately reportable segments.

ADOLOR CORPORATION AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(continued)

Net Loss per Share

Net loss per share is computed by dividing the net loss allocable to common stockholders by the weighted average number of shares of common stock outstanding. Net loss allocable to common stockholders is calculated as the net loss plus preferred dividends accrued for the respective period, whether or not declared, plus the beneficial conversion feature, if any, on mandatorily redeemable convertible preferred stock. In computing the basic and diluted net loss per share allocable to common stockholders the weighted average number of shares remains the same for both calculations due to the fact that when a net loss exists, dilutive shares are not included in the calculation.

Use of Estimates

The preparation of the Company's Consolidated Financial Statements in conformity with U. S. generally accepted accounting principles require management to adopt critical accounting policies and to make estimates and assumptions that affect the amounts reported in its financial statements and accompanying notes. The estimates made are principally in the areas of contract revenue recognition and research and development expense accrual. Actual results could differ materially from those estimates.

Stock-Based Compensation

The Company has two stock-based compensation plans (the "Plans") under which options have typically been granted at a price equal to fair market value of the Company's common stock on the date of grant. Options granted under the Plans vest at such dates as are determined in connection with their issuance and expire not more than ten years from the date of grant. Upon share option exercise, new shares of the Company's common stock are issued. The Company did not repurchase shares of its common stock in 2006.

Effective January 1, 2006, the Company adopted the fair value measurement and recognition provisions of Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment" (SFAS 123R), using the modified prospective basis transition method. Under this method, stock-based compensation expense recognized in fiscal 2006 includes: (a) compensation expense for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation expense for all share-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated using the Black-Scholes option pricing model. The Company generally recognizes compensation expense for awards granted after December 31, 2005 on a straight-line basis over the requisite service period.

Certain of the Company's share-based payment arrangements are outside the scope of SFAS No. 123R and are subject to Emerging Issues Task Force ("EITF") Issue No. 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock," which requires vested stock options held by certain non-employee consultants to be accounted for as liability awards. Upon the adoption of SFAS 123R, the fair value of these vested and unexercised awards was estimated using the Black-Scholes option pricing model and \$0.3 million was reclassified from equity to liability as of January 1, 2006. The fair value of these awards are remeasured at each financial statement date until the awards are settled or expire. During the year ended December 31, 2006, \$118,000 of income was recorded based on the remeasurement of these options. As of December 31, 2006, stock options to acquire 28,000 shares of common stock held by non-employee consultants remained unexercised and a liability of \$78,000 at December 31, 2006 is included in accrued expenses in the accompanying consolidated balance sheet.

ADOLOR CORPORATION AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(continued)

As a result of adopting SFAS 123R on January 1, 2006, and the impact of EITF 00-19, the Company's net loss and basic and diluted net loss per share for the year ended December 31, 2006 are \$8.6 million and \$0.19 higher than if the Company had continued to account for share-based compensation under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB No. 25), the Company's previously adopted standard for such matters.

The following table summarizes the total stock-based compensation expense resulting from stock options included in the Consolidated Statement of Operations.

| | Year ended December 31, 2006 |
|--|---------------------------------|
| Selling, general and administrative | \$5,784,623 |
| Research and development | 2,768,805 |
| Total stock-based compensation expense | <u>\$8,553,428</u> |

Prior to January 1, 2006, the Company accounted for the Plans under the recognition and measurement provisions of APB No. 25, and related Interpretations, as permitted by Financial Accounting Standards Board Statement No. 123, "Accounting for Stock-Based Compensation" (SFAS 123), as amended by SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure" (SFAS 148).

The following table illustrates the effect on the net loss and the net loss per share for the years ended December 31, 2005 and 2004 as if the Company had applied the fair value recognition provisions of SFAS 123R to options granted under the Company's stock option plans. For purposes of this pro forma disclosure, the value of the options is estimated using the Black-Scholes option pricing model and amortized to expense over the options' vesting periods:

| | Year ended December 31, 2005 | Year ended December 31, 2004 |
|--|------------------------------------|------------------------------------|
| Net loss, as reported | \$(56,796,630) | \$(43,586,484) |
| Add: Stock-based employee compensation expense included in reported net loss | 18,202 | 598,223 |
| Deduct: Total stock-based employee compensation expense determined under fair value based method | (7,055,750) | (7,763,839) |
| Pro forma net loss | <u>\$(63,834,178)</u> | <u>\$(50,752,100)</u> |
| Net loss per share: | | |
| Basic and diluted—as reported | \$ (1.45) | \$ (1.12) |
| Basic and diluted—pro forma | \$ (1.63) | \$ (1.30) |

ADOLOR CORPORATION AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(continued)

Expected volatility for the expected life of the option is based upon historical volatility and the expected life is based upon the simplified method. The risk-free interest rate is calculated using the U.S. Treasury yield curves in effect at the time of grant, for the periods within the contractual life of the options.

Recently Issued Accounting Pronouncements

In February 2006, the FASB issued FASB Staff Position No. FAS 123(R)-4, *Classification of Options and Similar Instruments Issued as Employee Compensation That Allow for Cash Settlement upon the Occurrence of a Contingent Event*. This position amends SFAS 123R to incorporate that a cash settlement feature that can be exercised only upon the occurrence of a contingent event that is outside the employee's control does not meet certain conditions in SFAS 123R until it becomes probable that the event will occur. The guidance in this FASB Staff Position shall be applied upon the initial adoption of Statement 123R. The Company adopted SFAS 123R in the first quarter of fiscal 2006.

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ("FIN 48"), an interpretation of FASB Statement No. 109, *Accounting for Income Taxes* ("SFAS 109"). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109. FIN 48 prescribes a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon examination. If the tax position is deemed "more-likely-than-not" to be sustained, the tax position is then measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. FIN 48 is required to be adopted by the Company in fiscal 2007. The adoption of FIN 48 will not have a material impact on its results of operations and financial position.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"). SFAS 157 clarifies the definition of fair value, establishes a framework for measuring fair value and expands disclosures on fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company does not expect the adoption of SFAS 157 to have a material impact on the consolidated results of operations and financial position.

In September 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Current Year Misstatements* ("SAB 108"). SAB 108 requires analysis of misstatements using both an income statement (rollover) approach and a balance sheet (iron curtain) approach in assessing materiality and provides for a one-time cumulative effect transition adjustment. SAB 108 is effective for annual financial statements issued for fiscal years ending after November 15, 2006. The adoption of SAB 108 did not have a material impact on the consolidated results of operations and financial.

3. SHORT-TERM INVESTMENTS

Short-term investments consist of investment grade fixed income securities with original maturities of greater than three months at December 31, 2006, and all such investments have maturities of less than one year. All investments are classified as "available for sale" and are considered current assets as management has the ability and intent to sell them at any time.

ADOLOR CORPORATION AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(continued)

The following summarizes the short-term investments at December 31, 2006 and 2005:

| | Cost | Gross unrealized gains | Gross unrealized losses | Fair value |
|---|---------------|------------------------------|-------------------------------|---------------|
| US Government obligations at December 31, 2006 | \$182,287,714 | \$55,186 | \$ (59,749) | \$182,283,151 |
| US Government obligations at December 31, 2005 | \$101,643,480 | \$ — | \$(297,460) | \$101,346,020 |

Short-term investments at December 31, 2006 and 2005 had maturities ranging up to twelve months.

4. CONTRACT REVENUES

Contract revenues consist of the following:

| | Year Ended December 31, | | |
|--|-------------------------|--------------|--------------|
| | 2006 | 2005 | 2004 |
| Cost reimbursement under collaborative agreement | \$ 8,533,750 | \$ 7,322,200 | \$11,374,951 |
| Co-promotion revenue | 2,387,025 | 4,230,000 | — |
| Amortization of up-front license fees | 4,166,636 | 4,166,676 | 4,166,676 |
| Milestone payments | — | — | 10,000,000 |
| Total revenue | \$15,087,411 | \$15,718,876 | \$25,541,627 |

In April 2002, the Company entered into a collaboration agreement with Glaxo for the exclusive worldwide development and commercialization of Entereg® for certain indications. Under the terms of the agreement, Glaxo paid the Company a non-refundable and non-creditable signing fee of \$50.0 million during the quarter ended June 30, 2002. The \$50.0 million signing fee is reflected in deferred licensing fees and is expected to be recognized as revenue on a straight-line basis over the estimated performance period under the collaboration agreement, which estimated performance period was extended by two years based on the second approvable letter from the FDA received in November 2006. Revenue related thereto of approximately \$4.2 million was recognized in each of the years ended December 31, 2006, 2005 and 2004. In the third quarter of 2004, upon acceptance for review of the Company's NDA by the FDA, and under the terms of the collaboration agreement, the Company recognized \$10.0 million in milestone revenue received from Glaxo.

External expenses for research and development and marketing activities incurred by each company in the United States are reimbursed by the other party pursuant to contractually agreed percentages. Reimbursement amounts owed to the Company by Glaxo are recorded gross on the Consolidated Statements of Operations as contract revenues. The Company recorded contract revenues of approximately \$8.5 million, \$7.3 million and \$11.4 million, respectively, in the years ended December 31, 2006, 2005 and 2004 under this arrangement. As of December 31, 2006 and 2005, approximately \$2.8 million and \$1.9 million, respectively, were receivable from Glaxo for reimbursement of expenses incurred by the Company pursuant to the collaboration agreement.

The Company had established a hospital-focused sales force under a co-promotion agreement with Glaxo to co-promote Glaxo's anti-thrombotic agent, Arixtra. Under the terms of the co-promotion agreement, Glaxo provided payments to Adolor at a contractual rate for the Adolor sales representatives deployed on Arixtra. The Company recognized co-promotion revenue of approximately \$2.4 million and \$4.2 million, respectively, in the year ended December 31, 2006 and 2005 related thereto. The Company also had a \$0.5 million and \$1.3 million

ADOLOR CORPORATION AND SUBSIDIARY
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(continued)

receivable from Glaxo at December 31, 2006 and 2005, respectively, related thereto. The co-promotion agreement with Glaxo terminated effective December 31, 2006 and the Company eliminated the sales force in December, 2006 (Note 13).

Glaxo has certain rights to terminate the collaboration agreement. Glaxo also has the right to terminate its rights and obligations with respect to the acute-care indications, or its rights and obligations for the chronic-care indications. Glaxo has the right to terminate the collaboration agreement for breach of the agreement by us or for safety related reasons as defined in the collaboration agreement. Glaxo's rights to terminate the acute-care indications or the chronic-care indications are generally triggered by failure to achieve certain milestones within certain timeframes, adverse product developments or adverse regulatory events. For example, because the postoperative ileus ("POI") product has not been commercially sold as of December 31, 2006, Glaxo now possesses the right to terminate the collaboration agreement with respect to the POI product and the OBD chronic product.

5. EQUIPMENT AND LEASEHOLD IMPROVEMENTS

Equipment and leasehold improvements consist of the following:

| | December 31, | |
|--|---------------------|---------------------|
| | 2006 | 2005 |
| Laboratory, computer and office equipment | \$ 11,252,428 | \$10,044,875 |
| Furniture, fixtures and leasehold improvements | 7,263,464 | 7,051,207 |
| | 18,515,892 | 17,096,082 |
| Less accumulated depreciation and amortization | (11,493,398) | (8,898,612) |
| | <u>\$ 7,022,494</u> | <u>\$ 8,197,470</u> |

In 2004, management conducted a review of its accounting for the lease of its corporate headquarters, which was entered into in 2003. The Company did not account for a tenant improvement allowance provided by the landlord on the Consolidated Balance Sheets or on the Consolidated Statements of Cash Flows. Management determined that the appropriate accounting under generally accepted accounting principles required that the allowance be recorded as a deferred rent liability on the Consolidated Balance Sheets and as a component of operating activities on the Consolidated Statements of Cash Flow. As a result, the Company recorded a leasehold improvement of approximately \$1.4 million relating to a tenant allowance and a corresponding deferred rent liability at December 31, 2004. The deferred rent liability is amortized over the lease term as a reduction of rent expense and the addition to leasehold improvements is amortized over the useful life of the improvement. The Company corrected the lease accounting as of December 31, 2004 as management determined that the amounts are immaterial to the financial statements of prior periods.

ADOLOR CORPORATION AND SUBSIDIARY
(A Development Stage Company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(continued)

6. ACCRUED EXPENSES

Accrued expenses consist of the following:

| | December 31, | |
|--|---------------------|---------------------|
| | 2006 | 2005 |
| Clinical development costs | \$ 601,683 | \$ 1,885,916 |
| Manufacturing costs | 1,249,186 | 517,837 |
| Consulting and other costs | 2,742,378 | 729,998 |
| Collaboration agreement expenses | 2,669,966 | 4,690,259 |
| Professional fees | 408,593 | 411,525 |
| Personnel related costs | 3,035,316 | 3,159,872 |
| Restructuring costs (Note 13) | 2,503,189 | — |
| | <u>\$13,210,311</u> | <u>\$11,395,407</u> |

7. COMMON STOCK AND COMMON STOCK OPTIONS

In 2006, the Company sold 5,750,000 shares of common stock at \$25.00 per share. The proceeds of the offering were approximately \$135.1 million, net of offering costs.

Shareholder Rights Plan

The Company's Board of Directors adopted a Shareholder Rights Plan (the "Plan") in February 2001. Under the Plan, preferred stock purchase rights (each, a "Right") were distributed as a dividend at the rate of one Right for each share of common stock outstanding as of the close of business on February 20, 2001 and automatically attach to shares issued thereafter. Each Right entitles the holder to purchase one ten-thousandth of a share of newly created Series A Junior Participating Preferred Stock of the Company at an exercise price of \$155.00 (the "Exercise Price") per Right. In general, the Rights will be exercisable if a person or group ("Acquiring Person") becomes the beneficial owner of 15% or more of the outstanding common stock of the Company or announces a tender offer for 15% or more of the common stock of the Company. When the Rights become exercisable, a holder, other than the Acquiring Person, will have the right to receive, upon exercise, common stock having a value equal to two times the Exercise Price of the Right. The Board of Directors will in general be entitled to redeem the Rights for \$.0001 per Right at any time prior to the occurrence of the stock acquisition events described above. If not redeemed, the Rights will expire on February 19, 2011.

Standstill Arrangement

The Glaxo collaboration agreement generally provides that during its term, Glaxo will not, directly or indirectly, alone or in concert with others, (i) acquire, or agree to acquire any shares of the Company's common stock or any securities exercisable for or convertible into the Company's common stock, (ii) make, or in any way participate in, any solicitation of proxies to vote the Company's common stock or (iii) acquire or agree to acquire any of the Company's tangible or intangible assets not offered for sale by the Company. However, Glaxo may under certain circumstances acquire equity securities of the Company set forth in the agreement including following the initiation by a third party of an unsolicited tender offer to purchase the Company or in connection with stock splits or recapitalizations or on exercise of pre-emptive rights afforded to the Company's stockholders generally.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(continued)

Stock Options

The Company's 1994 Amended and Restated Equity Compensation Plan, as amended (the "1994 Plan"), and 2003 Stock-Based Incentive Compensation Plan (the "2003 Plan"), together known as the Plans, allow for the granting of incentive and nonqualified stock options to employees, directors, consultants and contractors to purchase an aggregate of 11,350,000 shares of the Company's common stock. The options are exercisable generally for a period of seven to ten years from the date of grant and vest over terms ranging from immediately to four years.

In May 2006, the 2003 Stock-based Incentive Compensation Plan was amended to increase the number of shares of common stock authorized for issuance under the 2003 Plan by 2,500,000. There were 512,797 and 2,632,840 options available for future grant under the 1994 and 2003 plans, respectively, as of December 31, 2006. The Company has reserved 7.5 million shares of common stock for the exercise of stock options.

The following table summarizes employee stock option activity for the year ended December 31, 2006:

| | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life | Aggregate Intrinsic Value |
|----------------------------------|------------------|--|---|---------------------------------|
| Outstanding at January 1, 2006 | 4,350,774 | \$13.00 | | |
| Granted | 1,575,460 | 13.78 | | |
| Exercised | (1,063,181) | 11.63 | | |
| Forfeited | (620,968) | 13.51 | | |
| Cancelled | | | | |
| Expired | | | | |
| Outstanding at December 31, 2006 | <u>4,242,085</u> | <u>13.82</u> | <u>7.0</u> | <u>\$757,443</u> |
| Exercisable at December 31, 2006 | <u>2,653,297</u> | <u>\$14.21</u> | <u>6.2</u> | <u>\$757,443</u> |

The weighted-average grant date fair value of the options issued in 2006, 2005 and 2004 was \$9.31, \$5.19 and \$6.86, respectively.

The fair value of stock options granted to employees was estimated using the Black-Scholes option pricing model with the following weighted-average assumptions for the years ended December 31, 2006, 2005 and 2004:

| | 2006 | 2005 | 2004 |
|---------------------------------|-------|-------|-------|
| Expected dividend yield | | | |
| Expected stock price volatility | 67.5% | 68.3% | 48.0% |
| Risk-free interest rate | 4.52% | 3.93% | 3.33% |
| Expected life (in years) | 6.0 | 4.0 | 4.0 |

The aggregate intrinsic value in the preceding table represents the total pretax intrinsic value that would have been received by the option holders had all option holders exercised their options on December 31, 2006. Intrinsic value is determined by calculating the difference between the Company's closing stock price on the last trading day of fiscal 2006 and the exercise price, multiplied by the number of options. The total intrinsic value of options exercised during the year ended December 31, 2006 was \$12.6 million. The total number of in-the-money options exercisable as of December 31, 2006 was 180,795. As of December 31, 2006, total unrecognized compensation cost related to unvested stock options was \$13.1 million, which will be amortized over the weighted average remaining service period of 2.9 years.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(continued)

A summary of options outstanding and exercisable by price range at December 31, 2006, is as follows:

| Range of exercise prices | Options Outstanding | | | Options Exercisable | |
|--------------------------|---------------------|--|---|---------------------|---|
| | Number of options | Weighted average remaining option life | Weighted average exercise price (per share) | Number of shares | Weighted average exercise price (per share) |
| \$0.00—2.79 | 74,453 | 6.7 | \$ 1.12 | 74,453 | \$ 2.32 |
| \$2.80—5.59 | 91,342 | 3.6 | \$ 3.50 | 91,342 | \$ 3.50 |
| \$5.60—8.39 | 430,000 | 10.0 | \$ 8.21 | 30,000 | \$ 7.77 |
| \$8.40—11.19 | 996,077 | 6.9 | \$ 9.77 | 631,456 | \$ 9.74 |
| \$11.20—13.99 | 568,487 | 6.0 | \$12.98 | 503,221 | \$13.11 |
| \$14.00—16.79 | 1,101,290 | 7.1 | \$14.97 | 620,709 | \$15.17 |
| \$16.80—19.59 | 162,986 | 5.4 | \$18.48 | 132,460 | \$18.48 |
| \$19.60—22.39 | 565,087 | 6.0 | \$21.15 | 445,931 | \$21.14 |
| \$22.40—25.19 | 220,259 | 9.4 | \$23.61 | 105,331 | \$23.31 |
| \$25.20—27.99 | 32,104 | 9.3 | \$26.40 | 18,394 | \$25.68 |
| | <u>4,242,085</u> | | <u>\$13.82</u> | <u>2,653,297</u> | <u>\$14.21</u> |

During the year ended December 31, 2000, the Company granted options to certain employees to acquire 1,657,035 shares of the Company's common stock at exercise prices ranging from \$2.25 to \$3.50 per share for which deferred compensation, based on a fair value of \$14.40 per share on the grant date, amounting to approximately \$18.7 million was recorded. The deferred compensation was amortized to compensation expense over the respective vesting periods of the options.

During the years ended December 31, 2004, 2003 and 2001, the Company granted options to non-employees to acquire 59,966, 4,000 and 20,000 shares of common stock, respectively, for which deferred compensation of \$365,000, \$24,627 and \$294,000 was recorded in 2004, 2003 and 2001, respectively, based on fair value as determined using a Black-Scholes option pricing model and was amortized to expense over the vesting periods of the options. The amount of amortization for option grants to non-employees is subject to change each reporting period based upon changes in the fair value of the Company's common stock, estimated volatility and the risk free interest rate until the non-employee completes his or her performance under the option agreement. Compensation expense during the years ended December 31, 2006, 2005 and 2004, relating to these option grants was approximately \$1,000, \$18,000, and \$1.1 million, respectively.

The Company granted 80,000 shares of restricted stock to employees in 2006. Of this amount, 75,000 shares of restricted stock vest upon meeting certain performance conditions (FDA approvals). The fair value of these restricted shares will be charged to expense upon obtaining such approval. The remaining 5,000 shares of restricted stock with a fair value of \$120,150 will be charged to expense over the 3-year vesting period. In January 2007, the Company granted 1,023,170 stock options and 165,438 restricted stock awards.

8. LICENSE AND RESEARCH AGREEMENTS

In November 1996, Roberts Laboratories Inc. ("Roberts") licensed from Eli Lilly certain intellectual property rights relating to *Entereg*. In June 1998, the Company entered into an Option and License Agreement

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(continued)

with Roberts under which the Company licensed from Roberts the rights Roberts had licensed from Eli Lilly for *Entereg*. The Company have made license and milestone payments under this agreement totaling \$1.6 million. If *Entereg* receives regulatory approval, the Company is obligated to make a milestone payment of \$900,000 under this agreement, as well as royalties on commercial sales of *Entereg*. The Company's license to *Entereg* expires on the later of either the life of the last to expire of the licensed Eli Lilly patents or fifteen years from November 5, 1996, following which the Company will have a fully paid up license.

In August 2002, the Company entered into a separate exclusive license agreement with Eli Lilly under which the Company obtained an exclusive license to six issued U.S. patents and related foreign equivalents and know-how relating to peripherally selective opioid antagonists. The Company paid Eli Lilly \$4.0 million upon signing the agreement and is subject to additional clinical and regulatory milestone payments and royalty payments to Eli Lilly on sales, if any, of new products utilizing the licensed technology. Under this license agreement, the Company also agreed to pay Eli Lilly \$4.0 million upon acceptance for review of our NDA by the FDA, which payment was made in the third quarter of 2004.

In July 2003, the Company entered into a license agreement with EpiCept Corporation under which the Company licensed exclusive rights to develop and commercialize in North America a sterile lidocaine patch which is being developed for management of postoperative incisional pain. The Company made a \$2.5 million payment to EpiCept upon execution of the agreement and a \$0.5 million payment to EpiCept in September 2005. The Company terminated the EpiCept license in the fourth quarter 2006.

The Company intends to charge to expense research and development milestone payments that are required to be made upon the occurrence of future events prior to receipt of applicable regulatory approval.

9. INCOME TAXES

No federal and state taxes are payable as of December 31, 2006 and 2005.

As of December 31, 2006, the Company had approximately \$271.1 million of Federal and \$268.0 million of state net operating loss carryforwards potentially available to offset future taxable income. The Federal and Pennsylvania net operating loss carryforwards will expire as follows:

| | Federal | State |
|------------------|----------------------|----------------------|
| 2007 | \$ — | \$ 2,063,000 |
| 2008 | — | — |
| 2009 | 33,000 | — |
| 2010 | 482,000 | — |
| 2011 | 1,079,000 | — |
| 2012 | 1,867,000 | — |
| 2013 | — | — |
| Thereafter | 267,673,000 | 265,922,000 |
| | <u>\$271,134,000</u> | <u>\$267,985,000</u> |

Federal and state net operating loss carryforwards described above do not reflect a portion of the benefit related to certain stock option exercises as prescribed by SFAS 123R. The utilization of the state net operating loss carryforwards is subject to an annual limitation. At December 31, 2006, the Company also has approximately \$8.4 million of Federal and \$737,000 of state research and development tax credit carryforwards, which begin expiring in 2011, and are available to reduce Federal and state income taxes.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(continued)

The Tax Reform Act of 1986 (the "Act") provides for a limitation on the annual use of net operating loss and research and development tax credit carryforwards following certain ownership changes (as defined by the Act) that could significantly limit the Company's ability to utilize these carryforwards. The Company may have experienced various ownership changes, as defined by the Act, as a result of past financings and the initial public offering. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited.

Significant components of the Company's deferred tax assets and liabilities are shown below. At December 31, 2006, a valuation allowance of \$157.0 million has been recognized to fully offset the deferred tax asset balance. A valuation allowance to reduce the deferred tax assets is required if, based on weight of the evidence, it is more likely than not that some, or all, of the deferred tax assets will not be realized. Realization of the Company's deferred tax assets is dependent upon generating future taxable income and given the uncertainty of future profitability, management has determined that a valuation allowance is necessary. The change in the deferred tax asset valuation allowance in 2006 and 2005 was approximately \$28.9 million and \$24.7 million, respectively, and such change reduced the statutory Federal tax benefit at a rate of 34% to no tax benefit or provision in the statement of operations.

| | 2006 | 2005 |
|--|----------------|---------------|
| Deferred tax assets: | | |
| Net operating losses | \$ 112,298,000 | \$ 81,255,000 |
| Capitalized research and development costs | 20,706,000 | 25,438,000 |
| Tax credit carryforwards | 8,905,000 | 7,489,000 |
| Deferred revenue | 13,056,000 | 14,852,000 |
| Accrued expenses and other | 2,278,000 | 232,000 |
| Total deferred tax assets | 157,243,000 | 129,266,000 |
| Less valuation allowance | (157,007,000) | (128,083,000) |
| Net deferred tax assets | 236,000 | 1,183,000 |
| Deferred tax liability | (236,000) | (1,183,000) |
| Net deferred tax | \$ — | \$ — |

10. COMMITMENTS

Future minimum lease payments under non-cancelable operating leases for equipment and office and laboratory space are as follows:

| <u>Year ending December 31,</u> | |
|---------------------------------|--------------------|
| 2007 | \$1,233,000 |
| 2008 | 1,252,000 |
| 2009 | 1,259,000 |
| 2010 | 1,220,000 |
| 2011 | 1,219,000 |
| 2012 and beyond | 1,932,000 |
| | <u>\$8,115,000</u> |

Rent expense was approximately \$1.0 million, \$1.0 million, and \$1.1 million, for the years ended December 31, 2006, 2005 and 2004, respectively. In December 2002, the Company signed a ten-year lease agreement for office and laboratory space with minimum rental payments of approximately \$1.2 million for 2007, \$1.2 million for 2008, and \$1.2 million for 2009 through 2013. The lease includes a renewal option for two

ADOLOR CORPORATION AND SUBSIDIARY
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(continued)

consecutive additional five year periods and the Company has a purchase option exercisable at the fifth or tenth year of the lease term.

Glaxo Collaboration Agreement

Under the terms of the Glaxo agreement, the Company will partially reimburse Glaxo for third party expenses incurred by Glaxo in the development of *Entereg* for certain indications in the United States, pursuant to an agreed upon development plan and budget. The Company also expects to incur certain expenses in the development of *Entereg*, pursuant to an agreed upon development plan and budget, for certain other indications in the United States, a portion of which are reimbursable to the Company by Glaxo. The Company expects to record these expenses as incurred.

Other Service Agreements

The Company has entered into various agreements for services with third party vendors, including agreements to conduct clinical trials, to manufacture product candidates, and for consulting and other contracted services. The Company accrues the costs of these agreements based on estimates of work completed to date. The Company estimates that approximately \$14.4 million will be payable in future periods under arrangements in place at December 31, 2006. Of this amount, approximately \$4.0 million has been accrued for work estimated to have been completed as of December 31, 2006, and approximately \$10.4 million relates to future performance under these arrangements.

11. LEGAL PROCEEDINGS

On April 21, 2004, a lawsuit was filed in the United States District Court for the Eastern District of Pennsylvania against the Company, one of its directors and certain of its officers seeking unspecified damages on behalf of a putative class of persons who purchased Company common stock between September 23, 2003 and January 14, 2004. The complaint alleges violations of Section 10(b) and Section 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), in connection with the announcement of the results of certain studies in the Company's Phase III clinical trials for *Entereg*, which allegedly had the effect of artificially inflating the price of the Company's common stock. This suit has been consolidated with three subsequent actions asserting similar claims under the caption: *In re Adolor Corporation Securities Litigation*, No. 2:04-cv-01728. On December 29, 2004, the district court issued an order appointing the Greater Pennsylvania Carpenters' Pension Fund as Lead Plaintiff. The appointed Lead Plaintiff filed a consolidated amended complaint on February 28, 2005. That Complaint purported to extend the class period, so as to bring claims on behalf of a putative class of Adolor shareholders who purchased stock between September 23, 2003 and December 22, 2004. The Complaint also adds as defendants the Company's Board of Directors asserting claims against them and the other defendants for violation of Section 11 and Section 15 of the Securities Act of 1933 in connection with the Company's public offering of stock in November 2003. The Company and the management and director defendants moved to dismiss the Complaint on April 29, 2005. The plaintiffs responded to the motion to dismiss on June 28, 2005, and the defendants' reply was filed on August 12, 2005. The Company believes that the allegations are without merit and intends to vigorously defend the litigation.

On August 2, 2004, two shareholder derivative lawsuits were filed in the United States District Court for the Eastern District of Pennsylvania, purportedly on behalf of the Company, against its directors and certain of its officers seeking unspecified damages for various alleged breaches of fiduciary duty and waste. The allegations are similar to those set forth in the class action complaints, involving the announcement of the results of certain studies in the Company's Phase III clinical trials for *Entereg*. On November 12, 2004, the Derivative Plaintiff

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(continued)

filed an amended Complaint. On December 13, 2004, the Company filed a motion challenging the standing of the Derivative Plaintiff to file the derivative litigation on its behalf. On December 13, 2004, the Company's directors and officers moved to dismiss the Complaint for the failure to state a claim. Plaintiffs responded to the Company's and the directors' and officers' motions on January 27, 2005. The Company and the Directors and Officers filed reply briefs on February 18, 2005.

The Company has not accrued any amount in the consolidated financial statements as of December 31, 2006 for these matters.

12. 401(k) PROFIT SHARING PLAN

The Company maintains a 401(k) Profit Sharing Plan (the "401(k) Plan") available to all employees meeting certain eligibility criteria. The 401(k) Plan permits participants to contribute up to 100% of their salary, not to exceed the limits established by the Internal Revenue Code. All contributions made by participants vest immediately into the participant's account. In 2006, 2005 and 2004, the Company made contributions to the 401(k) Plan of approximately \$314,000, \$278,000, and \$225,000, respectively. The Company's common stock is not and never has been an investment option for 401(k) Plan participants.

13. RESTRUCTURING CHARGE

On December 14, 2006, the Company announced that it disbanded its sales force of approximately 35 people and made other selected reductions to the Company's work force. This reduction was due to the November 2006 FDA approvable letter and subsequent delay to possible market entry for the Company's lead product, Entereg.

The reduction in the Company's work force resulted in a severance charge of \$2.5 million, of which none was paid in 2006. The accrued severance balance at December 31, 2006 of \$2.5 million (see Note 6) will be paid out in 2007. The severance charge is included in research and development and general and administrative expense in the consolidated statements of operations.

14. UNAUDITED QUARTERLY INFORMATION

This table summarizes the unaudited results of operations for each quarter of 2006 and 2005:

| | Quarter Ended | | | |
|--|--|----------|--------------|-------------|
| | March 31 | June 30 | September 30 | December 31 |
| | (In thousands, except per share amounts) | | | |
| Fiscal 2006 | | | | |
| Revenue | \$ 2,569 | \$ 2,958 | \$ 5,275 | \$ 4,285 |
| Net loss | (17,445) | (15,705) | (18,173) | (18,415) |
| Basic and diluted loss per share | (0.42) | (0.35) | (0.40) | (0.40) |
| Fiscal 2005 | | | | |
| Revenue | \$ 2,916 | \$ 3,808 | \$ 4,738 | \$ 4,257 |
| Net loss | (11,968) | (13,775) | (15,210) | (15,844) |
| Basic and diluted loss per share | (0.31) | (0.35) | (0.39) | (0.41) |

ADOLOR COMMON STOCK LISTING

Our Common Stock is registered on the NASDAQ Stock Market LLC under the symbol ADLR.

FORWARD-LOOKING STATEMENT

Forward-looking statements can be identified by words such as "goals," "targets," "plans," "expectations" and others. Our forward-looking statements are subject to risks and uncertainties, known and unknown, that could cause actual results and developments to differ materially from those expressed or implied in such statements. Further information about these and other relevant risks and uncertainties may be found in Adolor's filings with the Securities and Exchange Commission, available in its EDGAR database at <http://www.sec.gov> and from Adolor. Given the uncertainties affecting pharmaceutical companies in the development stage, you are cautioned not to place undue reliance on any such forward-looking statements, any of which may turn out to be wrong due to inaccurate assumptions, unknown risks, uncertainties or other factors. Adolor undertakes no obligation to publicly update or revise the statements made herein or the risks factors that may relate thereto.

FORM 10-K

A copy of Adolor's Annual Report on Form 10-K for the fiscal year ended December 31, 2006 is included with this Annual Report. A copy of Adolor's Annual Report on Form 10-K, filed with the Securities and Exchange Commission, is available from the Company without charge. For a copy of the Annual Report, please contact: Adolor Corporation, Investor Relations, 700 Pennsylvania Drive, Exton, PA 19341.

ANNUAL STOCKHOLDERS MEETING

The annual meeting of stockholders will be held at 9:00 a.m. local time on Thursday, May 17, 2007, at the Desmond Great Valley Hotel and Conference Center, Malvern, PA 19355.

REGISTRAR AND TRANSFER AGENT

StockTrans
44 West Lancaster Avenue
Ardmore, PA 19003

COMPANY COUNSEL

Dechert LLP
Philadelphia, PA

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

KPMG LLP
Philadelphia, PA

INVESTOR RELATIONS

Updated information about Adolor Corporation is available on the Company's home page located on the World Wide Web at <http://www.adolor.com>.

BOARD OF DIRECTORS

David Madden, Chairman
Armando Anido
Michael R. Dougherty
Paul Goddard, Ph.D.
George V. Hager, Jr.
Claude Nash, Ph.D.
Robert Nelsen
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Vice President, Strategy and Business Analysis

Denise B. Kerton
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Richard M. Mangano, Ph.D.
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David Jackson, MD
Chief Medical Officer

MANAGEMENT TEAM

Michael R. Dougherty
President and Chief Executive Officer and Director

James E. Barrett, Ph.D.
*Senior Vice President, Chief Scientific Officer, and
President, Research*

Martha E. Manning, Esquire
Senior Vice President, General Counsel and Secretary

Thomas P. Hess, CPA
Vice President, Finance and Chief Financial Officer

CORPORATE HEADQUARTERS

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END